NOT YET SCHEDULED FOR ORAL ARGUMENT

No. 24-1151 and consolidated cases

U.S. COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

Petition for Review of a Rule of
the U.S. Environmental Protection Agency

EPA's Proof Answering Brief

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

As required by D.C. Circuit Rule 28(a)(1), EPA certifies:

A. Parties and amici

All petitioners, respondents, and intervenors appearing here are listed in petitioners' opening briefs.

In addition, amici for petitioners are the Chamber of Commerce of the United States of America, and the National Association of Manufacturers.

B. Rulings under review

Under review is the action *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act*, 89 Fed. Reg. 37028 (May 3, 2024).

C. Related cases

There are no related cases within the meaning of Circuit Rule 28(a)(1)(C).

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GLOSSARY

EPA	U.S. Environmental Protection Agency
Industry Br.	Brief for Industry Petitioners
Intervenor Br.	Brief for Intervenor Petitioner
JA	Joint Appendix
Labor Br.	Brief for Labor Petitioners
OSH Act	Occupational Health and Safety Act
OSHA	Occupational Health and Safety Administration
TSCA	Toxic Substances Control Act

INTRODUCTION

Congress enacted the Toxic Substances Control Act ("TSCA") in 1976 to prevent harm to human health and the environment from chemical substances. In 2016, a bipartisan majority of Congress amended the statute to further these goals and to ensure comprehensive and timely assessments of chemical substances in commerce. The 2016 amendments "substantially increased EPA's obligation to evaluate and regulate dangerous chemicals." *Lab. Council for Latin Am. Advancement v. EPA*, 12 F.4th 234, 243 (2d Cir. 2021). As one Senator explained at the time, the 2016 amendments require EPA "to methodically review all existing chemicals for safety, starting with the worst offenders." 162 Cong. Rec. at S3513 (June 7, 2016).

This case involves EPA's revised regulatory framework for evaluating under TSCA the health and environmental risks posed by chemical substances. EPA's framework is rooted in the statutory text and structure, and it ensures that each risk evaluation is consistent with the best available science and is based on the weight of the scientific evidence. This is fully consistent with congressional intent that EPA should comprehensively review chemical substances. Industry and Intervenor Petitioners' arguments would constrict the scope of EPA's risk evaluations in a manner inconsistent with Congress's direction.

First, Congress intended for EPA to evaluate risks holistically, considering a chemical substance's full lifecycle, which Congress captured using the concept of a chemical's "conditions of use." EPA's rule requires it to consider all of a chemical substance's conditions of use. Industry and Intervenor Petitioners would instead allow EPA to exclude certain conditions of use from its risk evaluation. But that might underestimate risks, leading to less protective risk management requirements, and depriving the public of certainty as to risks associated with the use of the chemical substance in commerce.

Second, EPA's rule implements Congress's intent that EPA make a singular risk determination on each chemical substance, which more accurately reflects the totality of the risk presented by a chemical substance's multiple conditions of use, hazards, and exposures—including risks to a population exposed to the chemical in multiple different ways (e.g., at work and at home). Industry and Intervenor Petitioners would instead require EPA to make risk determinations for each condition of use for a chemical. But their approach would require EPA to consider uses in isolation—even where people are not exposed in isolation—and would deprive the public of a full understanding of the risks associated with a chemical substance.

Third, Congress directed EPA to consider all reasonably available information about exposures to chemical substances. The rule under review allows

EPA to consider information regarding personal protective equipment, but it precludes EPA from making any assumptions about its use or efficacy when determining risk. The different petitioners' starkly contrasting positions on this point confirm the reasonableness of the balance EPA struck. It is true, as Industry and Intervenor Petitioners state, that occupational safety laws require personal protective equipment use by some employers for some employees in some situations. It is also true, as Labor Petitioners state, that these laws do not protect all workers or cover all situations. Accounting for both these realities, EPA's rule requires consideration of the *actual* use and efficacy of personal protective equipment.

Finally, Congress intended for EPA to protect potentially exposed or susceptible subpopulations. Here, EPA listed "overburdened communities" as one example of such a population, to provide the public with notice of a potentially exposed or susceptible subpopulation that could be identified and considered in a risk evaluation. Industry Petitioners would limit EPA's consideration to only the illustrative examples listed in the statute, but that would not accomplish Congress's goal of protecting *all* potentially exposed or susceptible subpopulations. The addition of "overburdened communities" as a potential example ensures that EPA is assessing and addressing risks to the most vulnerable populations and is being

transparent about other groups that may fit into the definition of potentially exposed or susceptible subpopulation.

The petitions for review should be dismissed in part and denied in part.

STATEMENT OF JURISDICTION

Except for Petitioners' as-applied challenges to the reasonableness of EPA's framework for considering information regarding personal protective equipment, the Court has jurisdiction under 15 U.S.C. § 2618(a)(1)(A). The action at issue here, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act*, was published on May 3, 2024, at 89 Fed. Reg. 37028 (the "2024 Rule"), and, pursuant to 40 C.F.R. § 23.5(a), issued for purposes of judicial review on May 17, 2024. The petitions for review were timely filed within sixty days of that date. The parties comprising the Labor Petitioners timely filed petitions for review on May 21, 2024: the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, filed in this Court; the International Assoc. of Machinists and Aerospace Workers, AFLCIO, filed in the Fourth Circuit; and WorkSafe, Inc., filed in the Ninth Circuit. The American Chemistry Council and the Texas Chemistry Council filed a timely petition for review in the Fifth Circuit on May 24, 2024, and the American Fuel & Petrochemical Manufacturers and the American

Petroleum Institute timely filed in this Court on July 10; these parties are collectively referred to as Industry Petitioners.

On June 5, 2024, the Judicial Panel on Multidistrict Litigation selected this Court to hear all challenges to the 2024 Rule pursuant to 28 U.S.C. § 2112(a)(3).

ISSUES PRESENTED

1. Section 2605(b)(4)(A) requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to human health or the environment, under "the conditions of use." Did EPA reasonably conclude that it must consider all conditions of use when conducting risk evaluations, or can EPA exclude conditions of use from the scope of a risk evaluation?
2. Section 2605(b)(4)(A) requires EPA to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment." Did EPA reasonably conclude that it must make a single risk determination on the chemical substance?
3. Petitioners claim EPA's regulatory framework for considering information regarding the use of personal protective equipment is unreasonable, based on fact-specific hypotheticals about how that regulation might be applied in specific risk evaluations. Are Petitioners' claims ripe?

4. Sections 2605(b)(4)(F) and 2625(k) require EPA to consider exposure information when EPA conducts a risk evaluation.
    i. Did EPA reasonably conclude that it must consider information about workers' usage of personal protective equipment, which can affect their exposure to chemical substances?
    ii. Did EPA reasonably conclude that it cannot assume, in making a risk determination, that all workers use and are effectively protected by such equipment?
5. Section 2605 requires EPA to consider potentially exposed or susceptible subpopulations in risk evaluations. Did EPA reasonably list "overburdened communities" as an example of a possible potentially exposed or susceptible subpopulation?

STATUTES AND REGULATIONS

Pertinent statutes, regulations, and legislative history that are not in Petitioners' addenda are in the addendum to this brief.

STATEMENT OF THE CASE

I. Legal framework.

Congress enacted TSCA in 1976 "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1

(1976), as reprinted in 1976 U.S.C.C.A.N. 4491. Congress stated its policy that "adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment[.]" 15 U.S.C. § 2601(b)(2).

As originally enacted, TSCA authorized EPA to regulate chemical substances if EPA found there was a "reasonable basis" to conclude that their manufacture, processing, distribution, use, or disposal "presents or will present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a) (1976). Determining whether a chemical presented an "unreasonable risk" was the result of cost-benefit balancing, and EPA was required to use the "least burdensome requirements" to address any identified unreasonable risk. *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215 (5th Cir. 1991). The Fifth Circuit's decision overturning EPA's attempt to ban asbestos—a well-known human carcinogen—set an extraordinarily high bar for EPA to successfully regulate chemicals under TSCA. In addition, TSCA did not provide a specific process or timeline by which EPA was required to assess and manage unreasonable risks of chemical substances on the TSCA chemical substance inventory. As a result, little to no action to regulate existing chemicals under TSCA occurred for over forty years.

Congress significantly amended TSCA in 2016 through the Frank R. Lautenberg Chemical Safety for the 21st Century Act, amending TSCA. Pub. L. No. 114-182, 130 Stat. 448 (June 22, 2016). The 2016 amendments set in motion "a process under which EPA will for the first time systematically review the safety of chemicals in active commerce." 162 Cong. Rec. at S3516. In addition to addressing the flaws in the 1976 law that prevented EPA from taking meaningful action, the amended law made clear that EPA is to undertake comprehensive reviews of chemical substances, consider their entire lifecycle, identify "unreasonable risk" based solely on risk considerations, and ensure that evaluations consider potentially exposed or susceptible subpopulations, including workers. *See* 15 U.S.C. § 2602(12) (listing workers as an example of potentially exposed or susceptible subpopulations).

TSCA, as amended, sets up a three-step process by which EPA identifies, assesses and, as necessary, regulates chemical substances that are already in commerce. First, EPA designates a chemical substance as either a "high-priority substance" or "low priority substance" based on whether that chemical substance may present an unreasonable risk. 15 U.S.C. § 2605(b)(1)(B). For any substance designated as high-priority, EPA must then conduct a three and a half year long "risk evaluation" to determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of

costs or other nonrisk factors, … under the [chemical's] conditions of use." *Id.* § 2605(b)(3)-(4). If, through the risk evaluation, EPA determines that the chemical substance presents an unreasonable risk, EPA must engage in risk management, and ultimately regulate to address any unreasonable risks. *Id.* § 2605(a), (c).

The risk evaluation process involves the issuance of a scope document, followed by a hazard assessment, exposure assessment, risk characterization, and finally the risk determination. *See* 40 C.F.R. 702.39. Within six months after initiating a risk evaluation, EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider[.]" 15 U.S.C. § 2605(b)(4)(D). EPA must then "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." *Id*. § 2605(b)(4)(A).

Conditions of use are the "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4). This definition reflects Congress's intention that

EPA consider the chemical substance's risk throughout its entire lifecycle. *Id.*; *see also* 162 Cong. Rep. at S3516.

A potentially exposed or susceptible subpopulation is defined as "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. § 2602(12).

In conducting risk evaluations and promulgating risk management rules under TSCA, Congress directed EPA to make decisions in a "manner consistent with the best available science." *Id.* § 2625(h). EPA must take into account reasonably available information, and it must base its decisions with respect to risk evaluations and risk management on the weight of the scientific evidence. *Id.* § 2625(i), (k).

The first step when EPA initiates a risk evaluation is setting the scope. EPA first publishes a draft scope document for public comment, where interested members of the public may submit information regarding the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations the Administrator "expects to consider" for a risk evaluation. *See id.* § 2605(b)(4)(D); *see also* 40 C.F.R. § 702.39(b). EPA considers and responds to information

received during the public comment period and then finalizes the scope document within six months of initiation of the risk evaluation. *Id*. Nevertheless, the scope of the risk evaluation may change throughout the risk evaluation process, consistent with TSCA's requirement to use the best available science. Changes may be made based on new information as EPA develops the draft and then the final risk evaluation. For example, EPA may remove from consideration in the draft or final risk evaluation a condition of use that was included in the scope document after receiving new information showing that the condition of use was mistakenly included. *See* 88 Fed. Reg. 74292, 74297 (Oct. 30, 2023). Alternatively, EPA may be unaware of a condition of use during the scope phase but later incorporate it into the risk evaluation. *Id.*

The next steps in a risk evaluation are a hazard assessment and an exposure assessment. 15 U.S.C. § 2605(b)(4)(F); 40 C.F.R. § 702.39(c), (d). A hazard assessment "includes the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical substance under the conditions of use." 40 C.F.R. § 702.39(c)(1), (d)(1). An exposure assessment includes consideration of, "[w]here relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use." *Id.* Exposure information related to potential human health or environmental hazards of the chemical substance must be reviewed in a manner consistent with the best

available science and based on the weight of the scientific evidence. *Id.* § 702.39(d)(2). This includes weighing any uncertainties. 88 Fed. Reg. at 74308. EPA may evaluate information including, but not limited to, chemical release reports, release or emission scenarios, data and information collected from monitoring or reporting, release estimation approaches and assumptions, biological monitoring data, workplace monitoring data, chemical exposure health data, industry practices with respect to occupational exposure control measures, and exposure modeling. *Id.* § 702.39(d)(3).

After EPA completes the hazard and exposure assessments, EPA characterizes the risk. 15 U.S.C. § 2605(b)(3); 40 C.F.R. § 702.39(e). In characterizing risk, EPA must "integrate the hazard and exposure assessments into quantitative and/or qualitative estimates relevant to specific risks of injury to health or the environment, including any potentially exposed or susceptible subpopulations identified, under the conditions of use." 40 C.F.R. § 702.39(e). EPA cannot consider costs or other non-risk factors. *Id.* EPA must describe the weight of the scientific evidence for the identified hazards and exposures, in addition to other requirements like consideration of uncertainty and variability, data quality, and alternative interpretations. *See id*.

EPA then determines whether a chemical substance presents an unreasonable risk to human health or the environment, including an unreasonable

risk to any potentially exposed or susceptible subpopulations, under its conditions of use. *See* 15 U.S.C. § 2605(b)(4)(A). If EPA determines that a chemical substance presents unreasonable risk, then EPA will identify the conditions of use that significantly contribute to such determination. *Id*. § 702.39(f)(3). In determining whether a chemical substance presents unreasonable risk, EPA may weigh, *inter alia*, the severity and the nature of the hazard, and uncertainties. *See* 89 Fed. Reg. at 37037.

A determination that a chemical substance does not present unreasonable risk ends the process and is subject to judicial review. 15 U.S.C. §§ 2605(i)(1), 2618(a)(1)(A). A determination that a chemical substance presents an unreasonable risk triggers the next phase, where EPA must promulgate a "risk management" rulemaking to impose requirements on the chemical substance as necessary to ensure the chemical substance "no longer presents such risk." *Id.* § 2605(a)(1). Risk management is a separate regulatory process and outside the scope of the 2024 Rule. Any risk management rulemaking is also subject to judicial review, along with the underlying risk evaluation. *Id.* §§ 2605(i)(2), 2618(a)(1)(A).

II. Factual background

EPA proposed its first rule establishing a procedural framework for conducting risk evaluations in early 2017. 82 Fed. Reg. 7562 (Jan. 19, 2017).

EPA published a final rule several months later, changing several key statutory interpretations. 82 Fed. Reg. 33725 (July 20, 2017). In the preamble to the final rule, EPA asserted that it had the discretion to exclude from the scope of the risk evaluation some of a chemical substance's conditions of use. 82 Fed. Reg. at 33730/2-3. The 2017 final rule was ambiguous on whether EPA would make a single risk determination on the chemical substance or multiple determinations on each individual condition of use. *Id.* at 33744/3; *see also id.* at 33752/3 (promulgating 40 C.F.R. § 702.47 (2017)). However, in the first ten risk evaluations that EPA conducted after the 2016 amendments, EPA made multiple determinations, determining whether each condition of use of the chemical substance separately presented or did not present unreasonable risk. EPA also uniformly assumed in each of those first ten risk evaluations that workers potentially exposed to a chemical substance were provided with and always used personal protective equipment such as respirators and impervious gloves. *See, e.g.*, Methylene Chloride Final Risk Evaluation (2020) at 38, JAxxxx.

Environmental groups challenged the 2017 rule, arguing that EPA must make a single risk determination on the chemical substance, not multiple use-by-use risk determinations. *Safer Chems., Healthy Families v. EPA*, 943 F.3d 397, 409-410 (9th Cir. 2019) ("*Safer Chemicals*"). The Ninth Circuit held this issue

was not justiciable because the 2017 rule was ambiguous as to how EPA would in fact conduct risk evaluations. *Id.* at 414.

The environmental groups also argued that EPA must consider all of a chemical's conditions of use in the risk evaluation. The court held that the 2017 rule's preambular statements, that EPA "may" exclude certain conditions of use, were not sufficiently final for judicial review, and that the regulatory text did not actually grant discretion to exclude any conditions of use. *Id.* at 416. The court concluded, however, that EPA's decision to exclude from the definition of "conditions of use" certain legacy uses and associated disposals violated TSCA. *Id.* at 421.

EPA revised the 2017 rule in 2024. These revisions addressed each of the three aspects of the risk evaluation procedure described above: (1) whether EPA can exclude conditions of use; (2) whether EPA can make multiple use-by-use risk determinations; and (3) whether EPA can assume, without supporting reasonably available information, all workers are effectively using personal protective equipment that reduces workers' exposure. 89 Fed. Reg. at 37028.

First, EPA added regulatory text expressly stating that EPA will not exclude conditions of use from the scope of a risk evaluation. The relevant regulation now states:

> EPA will not exclude conditions of use from the scope of the risk evaluation, but a fit-for-purpose approach may result in varying types

> and levels of analysis and supporting information for certain conditions of use.

40 C.F.R. § 702.37(b)(4).

Second, EPA revised its regulations to clarify that EPA will make a single risk determination on the "chemical substance," rather than separate risk determinations for each condition of use. That language states:

> As part of the risk evaluation, EPA will make a single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

Id. § 702.39(f)(1).

Third, EPA adopted regulations reflecting its belief that assuming that all workers always reliably and effectively use personal protective equipment would lead to an underestimation of the risk to workers when EPA makes a risk determination. 89 Fed. Reg. at 37037. Thus, EPA added regulatory text expressly stating that, in making risk determinations, EPA will consider information regarding worker exposures, including circumstances where workers are exposed due to the absence or ineffective use of personal protective equipment, and will no longer assume that workers use and benefit from reduced exposure due to personal protective equipment:

> In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and

> reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.

Id. § 702.39(f)(2).

EPA made one other change relevant to these petitions for review: EPA added "overburdened communities" to the statutory definition of "potentially exposed or susceptible subpopulation," 15 U.S.C. § 2602(12), as an example subpopulation:

> Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA, who, due to greater susceptibility or exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, *or overburdened communities*.

Id. § 702.33 (emphasis added).

STANDARD OF REVIEW

The 2024 Rule is reviewed under the Administrative Procedure Act ("APA"). 15 U.S.C. § 2618(c)(1)(B). Under the APA, the Court should uphold EPA's rule unless the Court finds it to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706. If EPA considered the relevant factors and articulated a rational connection between the facts found and the choices made, its decisions must be upheld. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Labor and Intervenor Petitioner assert that a heightened "substantial evidence" standard applies here under 15 U.S.C. § 2618(c)(1)(B)(i)(I). Labor Br. at 17; Intervenor Br. at 6. But EPA issued the 2024 Rule pursuant to 15 U.S.C. § 2605(b)(4)(B), so it does not fall under the limited exceptions where Section 2618(c) prescribes a heightened standard of review.

When interpreting statutory terms, "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024). To resolve the meaning of disputed statutory language, a court shall adopt the interpretation that the court, "after applying all relevant interpretive tools, concludes is best." *Id.* at 2266. "Careful attention to the judgment of the Executive Branch may help inform that inquiry." *Id.* at 2273.

SUMMARY OF ARGUMENT

I. TSCA's plain text requires EPA to consider "the conditions of use" of a chemical substance. 15 U.S.C. § 2605(b)(4)(D). To be sure, TSCA allows EPA some discretion to determine what constitutes a chemical substance's conditions of use when establishing the scope of a risk evaluation. But identifying conditions of use depends in part on gathering available evidence and utilizing professional judgment in assessing that evidence. TSCA does not permit EPA to exclude circumstances that EPA determines meets the statutory definition of "conditions of

use." Although EPA can tailor its analysis and apply a more qualitative approach to some conditions of use and a more quantitative approach to others during the risk evaluation, the best reading of the statute is that TSCA does not allow EPA to exclude any conditions of use.

EPA's interpretation is consistent with other TSCA provisions that Petitioners cite, none of which indicate any intent by Congress to allow EPA to exclude conditions of use. Section 2625(*l*)(4) expressly allows EPA to proceed with risk evaluations that, before the amendments to TSCA, did not consider all conditions of use. That would only be necessary if, going forward, EPA could no longer exclude conditions of use in new risk evaluations. Section 2605(b)(4)(D) requires EPA to publish a scope document, which lays out the conditions of use EPA expects to consider in the risk evaluation. That simply recognizes that EPA may gain new information between the scoping document at the outset of the risk evaluation and the risk determination at the conclusion of the risk evaluation, that causes EPA to reconsider what is and what is not a condition of use. It does not amend Section 2605(b)(4)(D) to authorize EPA to exclude conditions of use from the risk evaluation itself. Section 2605(b)(4)(F)(ii) requires EPA to describe whether EPA considered aggregate and sentinel exposures. That directs EPA to explain that aspect of its decision-making. It is not a directive to consider such exposures, must less an authorization to exclude any exposure pathways or

conditions of use. Section 2617(c)(3) leaves open to state regulation some uses of a chemical substance. That is a recognition that not all of the circumstances in which a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of are conditions of use. And Section 2605(b)(4)(G) imposes a timeframe for EPA to complete risk evaluations. That is not evidence that Congress intended EPA to truncate an otherwise comprehensive evaluation by excluding conditions of use.

EPA's no-exclusion interpretation is also consistent with TSCA's legislative history. Categorically excluding any conditions of use would conflict with legislators' evident intent that EPA comprehensively determine whether a chemical substance presents an unreasonable risk.

II. TSCA's plain text requires EPA to make a single unreasonable risk determination based on the chemical substance, not a separate determination on each individual condition of use. The statute repeatedly refers to a risk determination or a risk evaluation, in the singular, on the chemical substance.

This interpretation is consistent with TSCA's structure. A number of statutory provisions, such as provisions addressing final agency action and risk management, are triggered by a determination on the chemical substance.

The legislative history further supports this interpretation that EPA must make a single risk determination on a chemical substance. Congressional

statements from the time of enactment of the 2016 amendments show that Congress intended a single risk determination on the chemical, rather than multiple determinations by use.

And a single risk determination does not violate any due process rights. Stakeholders and the regulated community are provided ample notice and are given the opportunity to meaningfully engage in the risk evaluation and risk management process at numerous different stages.

III. Petitioners claim that EPA's regulatory framework for considering information regarding the use of personal protective equipment is unreasonable. These are fact-specific, as-applied challenges, and are not ripe. Labor Petitioners argue that if EPA considers personal protective equipment, then EPA will underestimate risk. This is a challenge to potential future applications of the regulation, not a facial challenge to the regulation itself. Similarly, Industry Petitioners argue that the 2024 Rule is unreasonable because it requires EPA to "refuse to consider" personal protective equipment. But EPA's regulation simply states that EPA will not assume personal protective equipment. Whether EPA decides to consider personal protective equipment in a particular risk evaluation is a fact-specific inquiry that must be brought as an as-applied challenge.

IV. Information on the use and effectiveness of personal protective equipment is information regarding exposure. As such, EPA must consider

reasonably available information regarding such equipment's use and effectiveness in its risk evaluation. But nothing in the statute permits EPA to assume that workers use personal protective equipment, or that such equipment reduces their exposure. In fact, failing to consider information regarding the absence or ineffective use of personal protective equipment would be contrary to law. And, if the Court finds the as-applied challenges ripe, EPA's approach is reasonable.

V. TSCA expressly provides EPA with the discretion to identify potentially exposed or susceptible subpopulations, in accordance with the statutory criteria. This, too, is a fact-specific as-applied challenge that is not ripe. If the Court nonetheless reaches the merits, EPA appropriately included "overburdened communities" as an example of a type of subpopulation that could be considered in future risk evaluations.

ARGUMENT

I. EPA must include all conditions of use in the scope of a risk evaluation.

With the passage of the 2016 amendments, Congress directed EPA to systematically prioritize thousands of existing chemicals and evaluate their risks holistically, under the chemical's "conditions of use," a phrase that Congress defined to capture a chemical's full lifecycle. 88 Fed. Reg. at 74296. Consistent with that intent, the best reading of Section 2605(b)(4)(A) is that EPA cannot exclude from the scope of a risk evaluation any circumstance that falls within the

statutory definition of the phrase "conditions of use." Section 2605(b)(4)(A) states that EPA must determine in a risk evaluation whether "a chemical substance" presents an unreasonable risk of injury to health or the environment, "under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Although EPA has the discretion to determine as a factual matter what circumstances meet the statutory definition of "conditions of use," once EPA makes that determination, EPA cannot decline to evaluate those conditions of use. While EPA may tailor the level of its analysis of each condition of use, all conditions of use must be included within the scope of the risk evaluation.

EPA's interpretation follows the statutory text and best aligns with the statutory structure, which together show Congress's intent that EPA perform comprehensive evaluations of chemical substances. EPA was therefore justified in changing its position from the 2017 rule—especially given that EPA expressly acknowledged this change and described in detail the reasons for it.

Industry Petitioners take a contrary view. They argue that the statutory text, structure, and legislative history show that Congress intended EPA to review only those conditions of use that pose the greatest potential for risk, but Industry Petitioners are incorrect. Industry Petitioners also miss the mark when they argue that EPA did not adequately explain its change in position.

A. The best reading of the statute requires EPA to include in the scope of a risk evaluation all conditions of use.

TSCA's text and structure support EPA's interpretation that it cannot exclude any conditions of use from a Section 2605(b) risk evaluation. Section 2605(b)(4)(A) requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury," without considering costs or other nonrisk factors, under the conditions of use. 15 U.S.C. § 2605(b)(4)(A). The use of the definite article "the" before "conditions of use" connotes that EPA is to evaluate the entire set of "conditions of use," not a subset of that defined phrase. *See, e.g., New York State Nurses Ass'n Benefits Fund v. Nyack Hosp.*, 46 F.4th 97, 107 (2d Cir. 2022) (an agreement that trustees are entitled to "the payroll and wage records" means that the trustees are entitled to all of those records, "not some subset"); *Vodenichar v. Halcon Energy Props., Inc.*, 733 F.3d 497, 503, 506 (3d Cir. 2013) (statute prohibiting removal jurisdiction if "the primary defendants" are citizens of the state where the action was filed precludes removal only if all primary defendants are citizens of the state); *Singh v. Am. Honda Fin. Corp.*, 925 F.3d 1053, 1068 (9th Cir. 2019) (same).

Other provisions bearing on the purpose and content of risk evaluations confirm that understanding of the statute's mandate. For instance, Section 2605(b)(4)(F), describing "requirements" for what EPA "shall" consider in conducting a risk evaluation, states that EPA shall "integrate and assess available

information on hazards and exposures for *the* conditions of use of *the* chemical substance." 15 U.S.C. § 2605(b)(4)(F)(i) (emphasis added). Again, using the definitive article—twice—indicates that "conditions of use" describe the *definitive*, comprehensive circumstances in which a chemical substance is used; not a narrower subset that EPA chooses to evaluate.

Indeed, Congress knows how to refer to a limited set of conditions of use. Section 2604(h)(1)(A) addresses exemptions from restrictions on manufacturing and processing new chemical substances. There, Congress referred to "the specific conditions of use" identified in an application for exemption from notification requirements. *Id*. § 2604(h)(1)(A). When Congress "includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted).

Congress could have added similar limiting language in Section 2605(b)(4)(A). For example, Congress could have said that EPA shall evaluate "the specific conditions of use identified in the scope document," or "the conditions of use that the Administrator selects to evaluate." Or, as Industry Petitioners suggest, Congress could have directed EPA to evaluate "only those conditions of use" which the Administrator determines pose the greatest risk.

Industry Br. at 16. Or Congress could have used those or other limiting qualifiers, such as "some" or "a," rather than "the," which might have indicated that EPA need not consider every condition of use. *See Vodenichar*, 733 F.3d at 506 (using the word "the" instead of the word "a" before a group descriptor demonstrates an intent to include all members of the group). But Congress did not include any such qualifiers. The absence of such limiting language in Section 2605(b)(4)(A) is telling. *See* Response to Comments at 13 ("the plain language of the 2016 TSCA amendments direct[s] EPA to—without caveat—evaluate risks from chemicals substances under the conditions of use"), JAxxxx.

To be sure, Congress defined "conditions of use" as "the circumstances, *as determined by the Administrator*, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added). Industry Petitioners contend that that phrase grants EPA broad discretion to limit its evaluation of a chemical substance's risks. Industry Br. at 17. But the phrase "as determined by the Administrator" is better understood as granting EPA more limited discretion to determine, in fact, under what "circumstances" a chemical substance is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). The Administrator thus has some discretion to apply professional judgment to the

facts when "determining" whether a circumstance involving a chemical substance meets the statutory definition. *See* 89 Fed. Reg. at 37032/3 (distinguishing between EPA's "lack of discretion to exclude conditions of use" and EPA's "ability to exercise judgment in making its determination as to whether a particular circumstance … falls within the definition of 'condition of use' for a particular chemical"). For example, EPA can determine that a circumstance is too speculative to be "reasonably foreseen." *Id.* at 37033/1 (giving an example of a freak accident). But the "as determined by the Administrator" language is not a license to select which conditions of use should be included or excluded from a risk evaluation.

Once EPA has determined a particular circumstance meets the definition of "conditions of use"—that is, it is known, intended, or reasonably foreseen that the chemical substance is manufactured, processed, distributed, used, or disposed of in a particular manner or application—EPA must include that condition of use in the scope of the risk evaluation. That interpretation is consistent with the broader statutory structure. For instance, Section 2625(*l*)(4) was written in order to allow EPA to proceed to the risk management phase under Section 2605(a) for certain chemicals with risk evaluations that EPA had completed prior to enactment of the 2016 amendments. 15 U.S.C. § 2625(*l*)(4). Those completed risk evaluations did *not* consider all conditions of use, but after learning of EPA's risk management

plans for these chemicals, Congress did not want EPA to "reexamine and perhaps broaden the scope of these assessments," potentially delaying important health protections. *See* 162 Cong. Rec. at S3519. If, as Industry Petitioners argue, the 2016 amendments allow EPA to exclude conditions of use in *new* risk evaluations, then there would be no need to expressly authorize EPA to proceed with *old* evaluations that excluded some conditions of use. Under Industry Petitioners' interpretation of Section 2605(b)(4)(A), Section 2625(*l*)(4) would serve no purpose.

EPA's interpretation aligns with the Congressional intent of the 2016 amendments to establish a process that would "comprehensively determine whether a chemical substance" presents an unreasonable risk. 89 Fed. Reg. at 37032/1. Excluding some conditions of use from a risk evaluation, even if EPA knows that exposures result from those conditions of use, would undermine that intent. It would also "perpetuate uncertainties as to the safety of existing chemicals in the marketplace—the very problem Congress sought to address" when it amended TSCA. *Id.*

EPA's interpretation is also consistent with the statutory directives in Sections 2625(h) and (i) to make decisions "consistent with the best available science" and "based on the weight of the scientific evidence." *See* 15 U.S.C. § 2625(h), (i). As EPA explained, some conditions of use may have low exposures

when considered in isolation, but in the aggregate contribute to unreasonable risk. 89 Fed. Reg. at 37032/3 (discussing Section 2605(b)(4)(F)(ii)'s requirement that EPA describe whether it considered "aggregate or sentinel exposures to a chemical substance"); *see also id.* at 37038/3 (same). Excluding conditions of use with low exposures from a risk evaluation—precisely what Industry Petitioners advocate—could "deprive the public of a complete picture of the chemical's risk" and hamper EPA's ability to mitigate such risks. *Id.*

B. Industry Petitioners' contrary interpretation ignores statutory text, context, and purpose.

Industry Petitioners read Section 2605(b) to give EPA broad discretion to pick and choose which conditions of use to include in the risk evaluation. That reading is not consistent with the statute's text, structure, or purpose.

Starting with the text, Industry Petitioners contend that, if Congress intended Section 2605(b)(4)(A) to require evaluating *all* conditions of use, it would have used that word—"*all*"—or others to be clear that the risk evaluation must be comprehensive. Industry Br. at 18.

But an addition like that is unnecessary under the best interpretation of the text that does exist. "*The* conditions of use" are those conditions that EPA has determined are "the circumstances … under which a chemical substance *is* intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added).

Neither Section 2602(4) nor Section 2605(b)(4)(A) provides any factors or guidelines for EPA to follow in exercising the discretion to pick and choose among conditions of use that Industry Petitioners purport to find there.

Imagine, for example, that EPA in its scope document determines that Chemical A is used as a solvent in the automotive industry. Commenters provide definitive evidence that Chemical A is also used as a cleaning product in the dry-cleaning industry, and that such use is known to have contaminated drinking water. Industry Petitioners would give EPA the discretion to decide not to evaluate whether that use contributes to the unreasonable risk. Industry Petitioners do not (and cannot) point to anywhere in the text that grants EPA the power to ignore circumstances that indisputably meet the definition of "conditions of use."

Industry Petitioners claim to find that discretion in the phrase "as determined by the Administrator" in Section 2602(4). They argue that to "determine" means to review and prioritize, or to decide among alternatives, and to do so "based on their differential potential for exposure and contribution to risk." Industry Br. at 19 (citing Merriam Webster Dictionary). That is not how "determine" is used in Section 2602(4). "Determine" there is intended to encompass EPA's directive "to find out or come to a decision about" whether circumstances involving a chemical substance in fact meet the definition, "by investigation, reasoning, or calculation." *See Determine*, Merriam Webster definition 4, https://www.merriam-

webster.com/dictionary/determine (last visited Dec, 16, 2024) (to determine means "to find out or come to a decision about by investigation, reasoning or calculation"); *see also id.* definition 1a (to determine means "to fix conclusively or authoritatively").

Turning to the statute's structure, Industry Petitioners argue that if Congress had meant for EPA to consider all conditions of use, Congress could have done away with the "conditions of use concept" altogether, and instructed EPA to conduct risk evaluations for chemical substances. Industry Br. at 18. But the conditions-of-use concept was central to the 2016 amendments. Under the 1976 version of the statute, EPA had conducted only a handful of use-specific chemical assessments that did little to assure the American people of the safety of tens of thousands of never-before-reviewed chemical substances in commerce. *See, e.g.*, 162 Cong. Rec. at S3516 (noting that the pre-2016 version of TSCA grandfathered "tens of thousands of chemicals … without requiring any review of their safety"). The conditions-of-use concept added in the 2016 amendments was meant to ensure EPA would perform comprehensive evaluations that would consider future-oriented circumstances associated with the chemical substance that are "intended" or "reasonably foreseen" as well as circumstances that are "known." *Id.* (explaining that "a new definition added to TSCA explicitly provides … a mandate

for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur").

The conditions-of-use concept also structures how EPA undertakes the risk evaluation. It ensures that EPA does more than simply look at the prevalence of the chemical substance in the air, the water, or the soil. Instead, it directs EPA to address the more specific contexts—i.e., "circumstances"—under which people and the environment are exposed throughout the entire lifecycle of the chemical, from its manufacture to its disposal.

By the same token, the phrase "conditions of use" excludes certain circumstances. For example, intentional misuse is not a condition of use. 89 Fed. Reg. at 37033/1. Nor are legacy disposals, i.e., disposals that have already occurred, even if the chemical substance is still in the environment in some way as a result of that disposal. *Safer Chemicals*, 943 F.3d at 420-26 (upholding EPA's determination that "legacy disposals" are not conditions of use). And some circumstances are so atypical that they would likely not be considered conditions of use. *See* 89 Fed. Reg. at 37033/1. In sum, the terms "uses" and "conditions of use" are not synonymous. Section 2602(4) gives EPA the discretion to review those circumstances and decide which qualify as conditions of use.

Industry Petitioners also point to the scoping provision in Section 2605(b)(4)(D). That subsection requires EPA to publish the scope of the risk

evaluation to be conducted, including the conditions of use that EPA expects to consider. 15 U.S.C. § 2605(b)(4)(D). Industry Petitioners assert that this scope document would be meaningless if EPA must in a risk evaluation review all possible uses of a chemical substance. Industry Br. at 20. That is wrong for two reasons.

First, as noted above, not all circumstances involving a chemical substance's manufacture, processing, distribution, use, or disposal are "conditions of use." *See, e.g.*, 89 Fed. Reg. at 37033/1. EPA's scope document serves to inform the public what circumstances EPA has determined are conditions of use and expects to consider. That, in turn, gives the public the opportunity to comment on whether the identified uses are in fact conditions of use, and to identify uses that *should* have been determined to be conditions of use. 40 C.F.R. § 702.43(a)(3) (allowing comment on the draft scope document); *id.* § 702.43(c)(allowing comment on the draft risk evaluation).

The phrase "expects to consider" in Section 2605(b)(4)(D) is therefore a natural recognition that the conditions of use EPA identifies at the outset of the risk evaluation may not be the final set of conditions of use EPA considers in the risk evaluation. As EPA explained, its "early expectations at the scoping phase may not always align perfectly with the conditions of use actually considered and assessed in the subsequent draft and final risk evaluations." 89 Fed. Reg. at

37033/3. Industry Petitioners find this "incredible," Industry Br. at 20 n.6. But listening to and potentially adjusting an approach in response to public comment is simply good government. *See, e.g.*, 88 Fed. Reg. at 74297/3 (EPA might be unaware of or inadvertently exclude a condition of use during the scoping phase, but later incorporate it into the risk evaluation).

Second, the phrase "expects to consider" in Section 2605(b)(4)(D) simply cannot bear the weight that Industry Petitioners put on it. Articulating expectations at the outset of three-plus yearlong risk evaluation surely does not imply unbounded discretion to pick and choose which conditions of use are relevant and should be reviewed, and which conditions of use can be excluded from the scope of the risk evaluation and thereby not considered at all. Industry Br. at 20. Again, Congress provided no guidelines for EPA to apply to make that choice. Instead, Congress directed EPA to determine what, in fact, are a chemical substance's "conditions of use," and further directed EPA to evaluate the risks presented by the chemical substance "under the conditions of use." 15 U.S.C. § 2605(b)(4)(A), (4)(D).

Industry Petitioners' remaining arguments are similarly unavailing. They argue that Section 2605(b)(4)(F)(ii), which requires EPA to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration," *id*. § 2605(b)(4)(F)(ii),

confers discretion to pick among conditions of use. But Industry Petitioners' argument confuses and conflates "conditions of use" with "exposures."

Conditions of use are the circumstances in which a chemical substance is manufactured, processed, distributed, used, or disposed of. In contrast, when EPA conducts its exposure assessment, EPA is estimating or measuring the intensity, frequency, and duration of exposure presented by a chemical substance's conditions of use and the size and characteristics of the population exposed. *See id*. § 2605(b)(4)(F)(iv). An aggregate exposure refers to the combined exposures from a chemical substance across multiple routes and across multiple pathways. *See* 40 C.F.R. § 702.33. A sentinel exposure is the exposure that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures. *Id*.

The discretion to evaluate either aggregate or sentinel *exposures* says nothing about what *conditions of use* EPA must evaluate. Conditions of use *cause* exposures, and they may cause multiple types of exposures that EPA must then evaluate. For instance, processing a chemical in one industrial setting may lead to both inhalation (airborne) exposures and dermal (skin-contact) exposures to workers. It may be the case that the available data show that evaluating one of those exposure pathways in detail will adequately capture the potential risk presented by both pathways (a sentinel approach). Or it may be the case that the

available data or particular characteristics of the chemical substance warrant taking an aggregate exposure approach. Section 2605(b)(4)(F)(ii) permits that, but simply requires EPA to state which approach it took and provide the basis for any such consideration.

Industry Petitioners contend that the phrase "as determined" in Section 2602(4) "commands" EPA to prioritize and review uses "based on their potential for exposure and contribution to risk." Industry Br. at 19–21. This puts the cart before the horse. Before EPA assesses risk, EPA must determine the conditions of use, and do so based on factors that have nothing to do with risk. For example, if the Administrator determines that "a chemical substance is … known … to be manufactured" under certain circumstances, those circumstances are "conditions of use" regardless of their potential for exposure and contribution to risk. After conditions of use have been determined, EPA assesses the conditions of use in the risk evaluation, to determine whether, "under the conditions of use," the chemical substance presents an unreasonable risk. 15 U.S.C. § 2605(b)(4)(A). Industry Petitioners' approach—insisting that EPA has the discretion to consider riskiness *before* EPA undertakes the risk evaluation—has Congress's framework exactly backwards.

This does not mean that EPA would have to "effectively review *every possible* scenario." Industry Br. at 22. As discussed above, EPA does have the

discretion to exclude uses that the Administrator determines do not meet the statutory definition—not for risk-based reasons, but because they do not satisfy statutory criteria (e.g., EPA determines they are "speculative" rather than "reasonably foreseen"). *See* 89 Fed. Reg. at 37033/1.

In all events, that exposure-focused provision does not, as Industry Petitioners urge (Industry Br. at 21), mean that EPA must focus a risk evaluation on conditions of use with the highest potential for exposure. And even if Section 2605(b)(4)(F)(ii) did require EPA to consider aggregate or sentinel exposures, or even to "focus" on them, as Industry Petitioners assert, a requirement to focus on or to prioritize something does not equate to a statutory directive to exclude and thereby ignore some conditions of use. Moreover, Section 2605(b)(4)(F)(ii) recognizes that EPA can consider combined exposures across multiple routes and pathways. This is further evidence that Congress intended for EPA to include all conditions of use in the scope of a risk evaluation.

Industry Petitioners also point to the preemption provisions of Section 2617(c)(3), which preempts state action regarding "the hazards, exposures, risks, and uses or conditions of use" of chemical substances that EPA determines do not present an unreasonable risk. 15 U.S.C. § 2617(c)(3). Industry Petitioners argue that if EPA cannot exclude any conditions of use then the entire chemical substance is effectively preempted, contrary to the more limited preemption in the

statutory text. Industry Br. at 21. But that again conflates "conditions of use" with all possible uses of a chemical substance. Not all circumstances involving a chemical substance fall within TSCA's definition of conditions of use. Furthermore, there are uses outside of TSCA's scope, such as pesticides and tobacco products, that are excluded from the definition of chemical substance under TSCA. 15 U.S.C. § 2602(2)(B). Uses, such as pesticides, that are by definition excluded from TSCA are not conditions of use under the statutory definition, and thus would not be preempted by Section 2617(c).

And Industry Petitioners argue that TSCA's three-year deadline for EPA to complete a risk evaluation is incompatible with reviewing "every possible scenario." Industry Br. at 22, citing 15 U.S.C. § 2605(b)(4)(G). Not so. For one, not every possible scenario is a condition of use; only those circumstances that EPA so determines, based on the definition in Section 2602, are conditions of use. For another, EPA's approach (consistent with the statute), is that certain conditions of use or exposures pathways may receive more or less analytic rigor than others. 89 Fed. Reg. at 37034/2; *see also* 88 Fed. Reg. at 74300/2 (explaining that "not all of those conditions of use will warrant the same level of evaluation"), Response to Comments at 11-12 (EPA may "take a more qualitative approach to conditions of use that EPA determines to be negligible contributors to exposures and risks"), JAxxxx-xxxx. This should allow EPA to complete risk evaluations within the

statutory deadlines. *See* 89 Fed. Reg. at 37034/2 (EPA expects to use the fit-for-purpose approach "to enable completion of risk evaluations within the statutory deadlines"); *see also* 88 Fed. Reg. at 74300/1-3 (same). But, if EPA determines that a circumstance is a condition of use, then EPA must include it for consideration in a risk evaluation.

In addition to their textual and structural arguments, Industry Petitioners argue that Congress intended EPA to consider only conditions of use with the greatest potential to pose risk, not all conditions of use. They point to a floor statement by Senator Vitter, Industry Br. at 23, but the Senator's remarks are consistent with EPA's interpretation. Senator Vitter notes that EPA has the "discretion to determine the conditions of use that the Agency will address." 162 Cong. Rec. at S3519. That is precisely how EPA reads Section 2602: not all potential uses of a chemical substance are conditions of use, so EPA must determine which circumstances (e.g., disposal) involving the chemical fall within the definition of "conditions of use." Senator Vitter then says that this discretion "assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk." *Id.* That, too, is consistent with how EPA reads Section 2602: the "fit for purpose" approach allows EPA to decide the conditions of use on which to focus the most analytical rigor. And Senator Vitter concludes that this "discretion to focus" risk evaluations on "certain" conditions of

use, i.e., the conditions of use that "raise the greatest potential for risk," helps ensure that EPA "can effectively assess and control priority chemicals and meet the new law's strict deadlines." *Id.* That again is consistent with EPA's interpretation: EPA can focus its efforts on those conditions of use that pose the greatest potential for exposure, and therefore risk, during the risk evaluation. But nowhere does Senator Vitter state that EPA can do what Industry Petitioners propose, i.e., *exclude* conditions of use entirely from consideration.

C. EPA acknowledged and reasonably explained its changed position.

Although the best reading of Section 2605(b)(4)(A) is that EPA cannot exclude a condition of use from a risk evaluation, that is not how EPA initially interpreted the statute. In the preamble to the final 2017 rule, EPA asserted that it retained the discretion to exclude conditions of use from the scope of a risk evaluations. 82 Fed. Reg. at 33729/1-2; *see also* 88 Fed. Reg. at 74297/1. EPA reasoned that Section 2605(b)(4)(D)'s requirement to identify in the scope document the conditions of use that EPA "expects to consider" in a risk evaluation "suggest[s] that EPA is not required to consider all conditions of use." 82 Fed. Reg. at 33729/1. Therefore, EPA announced that it "may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use" in order to focus on the exposures that are likely to present the greatest concern. *Id.*

As explained above, EPA now believes that the best reading of Section 2605(b)(4)(A) is that TSCA requires EPA to consider all conditions of use. *See* 89 Fed. Reg. at 37032/1; *see generally supra* Argument I.B.

When an agency reverses course, it must "display awareness that it *is* changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). EPA did so, pointing to the statutory text and structure, congressional intent, the 2019 *Safer Chemicals* decision, and "lessons learned" since 2017. 88 Fed. Reg. at 74297/1-74298/1; 89 Fed. Reg. at 37031/3-37032/3.

Industry Petitioners acknowledge that EPA explained the reasons that, in EPA's view, provide "justification for the Rule." Industry Br. at 26 n.9. Industry Petitioners may disagree with EPA on the merits of those justifications, but given this record Industry Petitioners cannot seriously dispute that EPA displayed awareness that it was changing course, and provided "an account of how it reached its results" that did more than merely parrot the statutory language. *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1405 (D.C. Cir. 1995). EPA has demonstrated that its interpretation is the best reading of the statute, and it has satisfied the APA's requirement of reasoned decision making.

II. EPA must issue a single risk determination on a chemical substance.

The 2024 Rule's requirement that EPA make a single risk determination for a chemical substance, rather than separate determinations for each individual condition of use, reflects the best reading of the statute. EPA's plain language reading of the statutory directive to "determine whether *a chemical substance*" presents unreasonable risk "under the conditions of use" aligns with congressional intent and the structure of the statute as a whole. Industry Petitioners' argument that EPA's approach deprives the regulated community of Fifth Amendment due process protections ignores the numerous opportunities for public notice and comment and judicial review before any final risk management rule is issued.

A. The best reading of the statute requires EPA to make a single risk determination on a chemical substance.

TSCA directs EPA to "determine whether *a chemical substance* presents *an unreasonable risk* of injury to health or the environment[.]" 15 U.S.C. § 2605(b)(4)(A) (emphases added). To find the ordinary and natural meaning of this provision, the Court should look to the subject, verb, and object of this operative clause. "[A] chemical substance" is the subject, "presents" is the verb, and "unreasonable risk" is the object. The plain way to understand this sentence, then, is that the unreasonable risk determination is made for the chemical substance itself, not for each individual condition of use of that substance. This alone is sufficient to show that a singular risk determination represents the best

interpretation of the statute. *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992).

The statute also refers to a singular determination on the "chemical substance" in a number of other provisions. *See, e.g.*, 15 U.S.C. § 2605(c)(1) ("If the Administrator determines that *a chemical substance* presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)…") (emphasis added); *id.* § 2605(i)(1) ("a determination by the Administrator under subsection (b)(4)(A) that *a chemical substance* does not present an unreasonable risk") (emphasis added). The repeated use of a singular determination on a chemical substance throughout the text of the statute, rather than on a condition of use, is evidence that the best reading of Section 2605(b)(4)(A) is that the determination be made on the chemical substance. *See Genus Lifesciences, Inc. v. Azar*, 486 F. Supp. 3d 450, 460 (D.C. Cir. 2020) (citing Antonin Scalia & Bryan A. Garner, Reading Law 144, 170 (2012)) ("It is well-established that '[a] word or phrase is presumed to bear the same meaning throughout a text.'").

TSCA's statutory structure also supports the plain-language reading that Section 2605(b)(4)(A) requires a single risk determination. Other portions of the statute, besides the risk evaluation provision, refer to a singular risk determination on the chemical substance. *See, e.g.*, 15 U.S.C. §§ 2605(a) (stating if EPA

determines that the manufacture, processing, disposal, etc. of a chemical substance, or any combination of such presents *an* unreasonable risk, EPA should apply risk management requirements to the extent necessary so that the chemical substance no longer presents such risk), 2617(a)(1)(B) (discussing preemption of chemical substance found not to present *an* unreasonable risk).

For example, Section 2605(i) supports the single risk determination approach. Section 2605(i) describes final agency action under TSCA as "(1) a determination … that *a chemical substance does not present an unreasonable risk* of injury to health or the environment." *Id.* § 2605(i)(1) (emphasis added); *see also id*. § 2605(i)(2). Indeed, Section 2605(i) does not contain any mention of "conditions of use" at all. This marked absence of "conditions of use" is contrary to Industry Petitioners' theory that Congress intended the risk determination to be made use-by-use. Industry Br. at 27. If Congress had intended final agency action to be based on a use-by-use determination, Congress, at minimum, would have included the phrase "conditions of use" in the final action provision.

EPA's interpretation also conforms to Section 2601(b)'s statement of Congress's purposes in amending TSCA. That section explains Congress's intent to ensure that "adequate authority should exist to regulate *chemical substances and mixtures which present an unreasonable risk* of injury to health or the environment[.]" 15 U.S.C. § 2601(b)(2) (emphasis added). This is consistent with

the understanding that a determination of unreasonable risk is made on the chemical substance, not use-by-use.

Similarly, Section 2605(c)(1) establishes deadlines for EPA to promulgate 2605(a) risk management rules following a "determin[ation] that a chemical substance presents *an* unreasonable risk[.]" 15 U.S.C. § 2605(c)(1) (emphasis added). Together, these provisions make clear that Congress intended EPA to make a determination on whether a chemical presents an unreasonable risk, not to determine whether a use presents an unreasonable risk.

The text of Section 2605(b)(4)(A) is clear, but even if the Court finds ambiguities, legislative history supports a single risk determination on a chemical substance. *See Recording Indus. Ass'n of Am., Inc. v. Verizon Internet Servs., Inc.*, 351 F.3d 1229, 1237 (D.C. Cir. 2003) ("Legislative history can serve to inform the court's reading of an otherwise ambiguous text; it cannot lead the court to contradict the legislation itself.") (citing *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994)).

Legislative history in the form of congressional statements, bill markups, and congressional hearings support the single risk determination approach. For example, statements by Senator Vitter, a lead sponsor of the bill for the majority party, made on the date of the bill's passage reflect a clear understanding that the law would require a single risk determination on the chemical substance. Senator

Vitter said, "EPA's understanding of a chemical's conditions of use … will be critical to EPA's final determination of whether a chemical is safe or presents *an* unreasonable risk…." 162 Cong. Rec. at S3519 (emphasis added). He further stated that a Section 2605(i) order, "determining that a chemical substance does not present *an* unreasonable risk under conditions of use, is similarly final Agency action applicable to all those conditions of use that were identified in the scope of EPA's risk evaluation on the chemical substance." *Id.* at S3520 (emphasis added).

Similarly, Senator Inhofe, Chairman of the Committee on Environment and Public Works, stated "it is clear that when a chemical has undergone a risk evaluation and determined to pose no unreasonable risk, any state chemical management action to restrict or regulate the substance is preempted." *Id.* at S3521. These repeated statements describing the singular determination on the chemical substance support the 2024 Rule's single risk determination approach.

B. Industry Petitioners' position that TSCA requires use-by-use-risk determinations ignores statutory text, context, and purpose.

Despite the plain language support for a single risk determination on the chemical substance, Industry and Intervenor Petitioners urge the court to interpret TSCA to mandate separate risk determinations for each condition of use. Industry Br. at 28; Intervenor Br. at 9.

First, Industry Petitioners emphasize that EPA must "conduct risk evaluations … under the conditions of use," 15 U.S.C. § 2605(b)(4)(A), arguing

that this shows that Congress instructed EPA to evaluate risk on each individual condition of use, rather than on the chemical substance. Industry Br. at 28. But the operative verb in Section 2605(b)(4)(A) is for EPA "to determine" whether the operative noun, "a chemical substance," presents an unreasonable risk. 15 U.S.C. § 2605(b)(4)(A). Industry Petitioners are arguing that risk *determinations* should occur use-by-use, while ignoring the clause that discusses determinations. The "under the conditions of use" clause, by contrast, describes the circumstances under which EPA is to be evaluating a chemical substance's risks.

As discussed at length *supra* Argument I, the significance of "under the conditions of use" is that EPA must include all conditions of use in a risk evaluation. In contrast, the clause "determine whether a chemical substance presents an unreasonable risk" is the essential focus for the subject of a risk determination. Neither clause can be removed from the sentence. *See, e.g., Corley v. United States*, 556 U.S. 303, 314 (2009) ("[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant") (citing *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)). But, the proper focus for risk determinations is "whether a chemical substance presents an unreasonable risk," which makes the plain meaning clear: EPA shall make a singular determination on "a chemical substance." 15 U.S.C. § 2605(b)(4)(A).

Second, Intervenor Petitioner discusses how Section 2605(b)(4)(A) refers to "chemical substance" in the singular but directs EPA to "conduct risk evaluations" in the plural. Intervenor Br. at 13. Intervenor Petitioner argues that this parallel structure suggests that Congress intended multiple risk evaluations for a single chemical. Intervenor Petitioner further argues that Congress could have expressly directed EPA to conduct a single risk evaluation here rather than use the plural. *Id.* at 16. But the plural "risk evaluations" in Section 2605(b)(4)(A) refers to Congress's mandate that EPA conduct multiple risk evaluations on multiple chemicals at all times. *See* 15 U.S.C. § 2605(b)(3)(C), (b)(2)(A)-(B) (discussing how EPA must start with conducting ten risk evaluations at once and then, after several years, ensure that it was always conducting twenty risk evaluations on chemicals designated as high-priority at once).

And, throughout the statute, the text does refer to a singular "risk evaluation," when discussing the requirements for carrying out a risk evaluation on an individual chemical substance. *See, e.g.*, 15 U.S.C. § 2605(b)(3)(A), (b)(3)(C), (b)(4)(D), (b)(4)(E)(i), (b)(4)(F), (b)(4)(G). In marked contrast, risk evaluations in the plural is only used when discussing risk evaluation requirements under TSCA more broadly. *See, e.g.*, *id.* § 2605(b)(4)(B) (discussing EPA's general requirement to establish a process for conducting risk evaluations). The best

reading of the statute is to focus on the singular "unreasonable risk" determination made for the singular "chemical substance."

Third, Intervenor Petitioner argues that "under the conditions of use" in Section 2605(b)(4)(A) should be read as modifying "presents an unreasonable risk" and thus limit the evaluations to the risks presented under the conditions of use. Intervenor Br. at 13. "Under the conditions of use" does not dictate the number of risk determinations, it simply references that conditions of use should be accounted for within a risk evaluation. Thus, Intervenor Petitioner's argument is consistent with the 2024 Rule, as EPA would still make one risk determination that encapsulates all conditions of use considered in the risk evaluation.

Finally, Intervenor Petitioner argues that TSCA does not mandate consideration of all conditions of use in one determination because Section 2602 employs the word "or" not "and" to define what circumstances constitute a condition of use. Intervenor Br. at 15. This is not a logical reading of the statutory definition. The conditions of use are "the circumstances … under which a chemical substance is … manufactured, processed, distributed in commerce, used, *or* disposed of." 15 U.S.C. § 2602(4) (emphasis added). Had Congress used "and" rather than "or," the plain reading of the sentence would be that a condition of use only occurs where all the circumstances are met. But it would be nonsensical to require EPA to review all possible conditions of use as a singular condition of use.

Thus, the "or" in the definition is used to show that only one circumstance must be met for an activity to qualify as a condition of use.

Despite this clear compatibility between a single risk determination and the rest of TSCA, Industry and Intervenor Petitioners argue that a single risk determination on the chemical substance is inconsistent with other portions of TSCA. Their arguments are misplaced and misconstrue the 2024 Rule.

Industry Petitioners first argue that a single risk determination is inconsistent with TSCA provisions that emphasize "conditions of use." As an example, they note that Section 2605(b)(4)(F)(i) requires EPA to "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F)(i). Similarly, Section 2605(b)(4)(F)(iv) requires EPA to "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F)(iv).

EPA does not dispute that TSCA requires consideration of a chemical's conditions of use, and that the different exposure scenarios presented by the conditions of use should be reflected in the risk evaluation's exposure assessment. But Industry Petitioners err when they assert that a single risk determination "removes evaluation of the potential exposures to the substance." Industry Br. at 29. EPA's processes under the 2024 Rule explicitly provide for consideration of a

chemical's different exposure scenarios. For example, in the methylene chloride final risk evaluation, EPA evaluated inhalation and dermal exposures for conditions of use involving workers, including reupholstery and furniture repair, wood kitchen cabinet and countertop manufacturing, and aerosol degreasing. *See* Methylene Chloride Final Risk Evaluation (2020) at 123, JAxxxx. Inclusion of "conditions of use" in Section 2605(b)(4)(F)(i) and (iv), among other provisions, is not indicative of Congress's intent for risk determinations to be made on each condition of use, but rather on what the scope of the risk evaluation should be.

Second, Industry Petitioners argue that a single risk determination is contrary to Section 2617's preemption of state regulation of chemicals for which EPA makes an "unreasonable" risk determination. Industry Br. at 30. Industry argues that because federal preemption applies to "conditions of use of such chemical substances included in any final action [EPA] takes pursuant to section 2605(a)," 15 U.S.C. § 2617(c)(3), and "because EPA is required to issue Risk Determinations for particular uses," Industry Br. at 31, the preemption provision only makes sense under a use-by-use risk determination.

But Industry Petitioners' circular argument is not supported by statutory language. The preemption subsection is titled "*Chemical substances* found not to present an unreasonable risk or restricted," not "Conditions of use found not to present an unreasonable risk or restricted." 15 U.S.C. § 2617(a)(1)(B). And, the

federal preemption provision applies to "hazards, exposures, risks, and uses or conditions of use *of such chemical substances included in any final action*," which includes any hazard, exposure, risk, and use or condition of use addressed in the final risk evaluation that supports the final action. 15 U.S.C. § 2617(c)(3) (emphasis added). What's more, as discussed above, the final agency action provision states "(1) a determination … that *a chemical substance does not present an unreasonable risk* of injury to health or the environment," without reference to particular conditions of use. 15 U.S.C. § 2605(i) (emphasis added). All this affirms that Congress only envisioned one risk determination to be made for the chemical substance as a whole.

Then, Intervenor Petitioner argues that a single risk determination is inconsistent with EPA's requirement to publish the scope of the risk evaluation in a separate document, because under EPA's approach "every evaluation's scope is 'the whole chemical.'" Intervenor Br. at 17. EPA disagrees. EPA is required by Section 2605(b)(4)(D) to include in the scope document the "hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations" it expects to consider in a risk evaluation. The 2024 Rule is consistent with such requirements. As discussed above, *see supra* Argument I.B., the scope document serves to inform the public of what conditions of use EPA expects to consider. The conditions of use will change chemical to chemical, and in making a single

risk determination, EPA will still publish a scope document that includes each of the components required by § 2605(b)(4)(D) prior to initiating a risk evaluation. *See* 40 C.F.R. § 702.39.

Next, Intervenor Petitioner points to Section 2605(b)(4)(F)(v), which states that "[i]n conducting a risk evaluation … [EPA] shall describe the weight of the scientific evidence for the identified hazard and exposure." 15 U.S.C. § 2605(b)(4)(F)(v). Thus, Intervenor Petitioner states, "a risk evaluation considers a particular activity with a given chemical, because that is a prerequisite for 'identif[ying]' a particular 'exposure.'" Intervenor Br. at 17. In fact, this is exactly what EPA does: it looks at each hazard and exposure separately and characterizes those risks as part of the risk evaluation. Then, after assessing all this information in the evaluation, EPA makes a risk determination on the chemical substance. *See* 40 C.F.R. § 702.39(e), (f). As explained in Argument I.B. *supra*, conditions of use and exposure are distinct terms of art under TSCA. Though EPA's rationale would be the same, even if the statute used "conditions of use," Intervenor Petitioner's argument conflates these two terms and does not support their argument that risk determinations must be made on each condition of use.

Finally, Intervenor Petitioner makes a lengthy argument about the interplay between Section 2605(a), which governs risk management, and the 2024 Rule. Intervenor Br. at 8-13. Intervenor Petitioner argues EPA's authority under Section

2605(a) is dependent on EPA's risk determination and a single risk determination would give EPA authority to arbitrarily regulate any or all conditions of use. *Id.* at 9. Thus, whether EPA can regulate depends on what determination it made, and EPA must comply with Section 2605(b)(4)(A) restrictions to earn Section 2605(a) authority. *Id*. at 11.

Intervenor Petitioner's argument misconstrues TSCA's risk management authority. In the risk evaluation phase under Section 2605(b), EPA determines whether a chemical substance "presents" or "does not present" unreasonable risk. If EPA determines that the chemical substance presents unreasonable risk, then the Agency must initiate a risk management rulemaking proceeding under Section 2605(a). In effect, a chemical's risk determination acts as a toll gate allowing a chemical to pass to risk management or not. But walking through that gate does not mean EPA has unfettered authority to regulate the chemical substance. Rather, EPA determines what regulatory "requirements," listed in Section 2605(a), are needed to ensure the chemical substance "no longer presents such risk." 15 U.S.C. § 2605(a). That calculus is guided by the condition of use-specific analysis of chemical exposures documented in the risk evaluation. The determination as to how best address the unreasonable risk presented by a chemical substance occurs at the risk management rulemaking phase, *not* the risk evaluation phase at issue in the 2024 Rule.

So, contrary to Intervenor Petitioner's argument, a single risk determination does not give EPA unlimited authority to regulate under Section 2605(a). Section 2605(a) provides its own express limitation to regulate "to the extent necessary so that the chemical substance … no longer presents such risk." 15 U.S.C. § 2605(a). Regardless of whether EPA makes a single risk determination on the chemical or multiple risk determinations on individual uses, EPA cannot regulate conditions of use of a chemical substance where it is otherwise not necessary for purposes of addressing the unreasonable risk.

Industry Petitioners argue that legislative history supports their interpretation of Section 2605(b)(4)(A), because TSCA was intended to be a "gap-filling" statute. Industry Br. at 32. They further argue that a single risk determination will permit duplicative regulation and regulation of uses that do not present risks. *Id.* at 33. But Industry Petitioners incorrectly rely on outdated and irrelevant legislative history for the 1976 version of TSCA, as well as references to the risk management phase, which is not at issue in this rulemaking.

Additionally, in amending TSCA in 2016, Congress made clear that TSCA would be the primary statute for the regulation of toxic substances, stating that "TSCA can no longer be construed as a 'gap-filler' statutory authority of last resort." 162 Cong. Rec. at S3517. Moreover, Industry Petitioners' concerns regarding duplicative regulation and regulating uses that are otherwise not

necessary to address the unreasonable risk from the chemical substance are unfounded. In the separate risk management process, EPA will consider existing risk management controls and approaches, such as existing regulations, to avoid duplication. 89 Fed. Reg. at 37038. And, if Industry Petitioners believe that a future risk management rule regulates uses not necessary to address the unreasonable risk from the chemical substance, they could bring an as-applied challenge to that rule. 15 U.S.C. § 2605(i)(2) (final risk management rules are subject to judicial review).

Therefore, Industry and Intervenor Petitioners' interpretation is contrary to the plain text, statutory structure, and legislative history.

C. The 2024 Rule provides opportunities to participate in rulemakings and does not violate due process.

The 2024 Rule and the single risk determination approach make no changes to the many opportunities for interested individuals to participate in public notice and comment processes prior to the conclusion of the risk management phase and, therefore, do not violate the due process clause. To establish a due process claim, petitioners must show that they have a protected interest that government action deprives them of, without proper procedural protections. *See Cmty. Fin. Servs. Ass'n of Am., Ltd. v. FDIC*, 132 F.Supp.3d 98, 122 (D.C. Cir. 2015) (citing *Indus. Safety Equip. Ass'n, Inc. v. EPA*, 837 F.2d 1115, 1122 (D.C. Cir. 1988)).

Industry Petitioners argue that a single risk determination violates the Fifth Amendment by depriving stakeholders and the regulated community of meaningful notice about what uses will ultimately be subject to regulation through risk management. Industry Br. at 34. Accordingly, Industry Petitioners argue, the regulated community "must 'wait and see'" how EPA will regulate following a risk determination on a chemical substance. *Id.* at 35.

Industry Petitioner's argument ignores the many procedural protections and opportunities for public notice and comment established in TSCA itself as well as EPA's regulations. First, during the initiation and prioritization steps, EPA will publish for public comment notice of EPA's intent to prioritize a chemical substance. EPA then provides a public comment period where EPA proposes to designate the chemical as either a high-priority or low-priority chemical substance. *See* 15 U.S.C. § 2605(b)(1); *see also* 40 C.F.R. §§ 702.5, 702.7. After considering information received during these public comment periods and finalization of a high-priority designation, EPA initiates the risk evaluation. *Id*.

In the risk evaluation stage, EPA publishes a draft scope document for public comment, where interested individuals can submit information regarding the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations the Administrator "expects to consider" for a risk evaluation. *See* 15 U.S.C. § 2605(b)(4)(D); *see also* 40 C.F.R. § 702.39(b). After finalizing the

scope and completing the draft risk evaluation, EPA publishes the draft risk evaluation for public comment. *See* 40 C.F.R. § 702.43(c). Within the risk determination itself, EPA must identify which conditions of use significantly contribute to the unreasonable risk determination, giving regulated parties insight and better certainty as to which conditions of use EPA will most likely regulate in a risk management rule. 40 C.F.R. § 702.39(f)(3).

Then in the risk management phase, the public is provided with even more opportunities for engagement. Section 2605(c)(3) requires EPA to provide notice and opportunity to comment on a proposed risk management rule. And ultimately EPA's risk management rule, its underlying determination of unreasonable risk, and the risk evaluation on which the determination was based, are subject to judicial review. 15 U.S.C. § 2605(i)(2). These are ample opportunities to meaningfully participate at multiple stages in the risk evaluation and risk management process, and do not present any constitutional due process problems.

III. Petitioners' arbitrary-and-capricious arguments on consideration of personal protective equipment are as-applied challenges and are not ripe.

Petitioners' arguments regarding the reasonableness of the 2024 Rule's framework for considering personal protective equipment are not ripe and should not be considered on the merits. Labor Petitioners concede that an as-applied challenge to the 2024 Rule is not ripe, because "EPA has not applied the policy yet

and may not do so in the way Labor Petitioners fear." Labor Br. at 14 n.13. And a premature as-applied challenge is what Petitioners' reasonableness arguments amount to.

Labor Petitioners argue that if EPA considers personal protective equipment in a risk evaluation, then EPA will invariably underestimate risk. *Id*. at 20-21. They also argue that the effectiveness of personal protective equipment depends on many variables, *id.* at 21-22, that there are practical reasons why EPA should not consider personal protective equipment during a risk evaluation, *id.* at 24, and that personal protective equipment does not control the level of exposures in the workplace. *Id.* at 25 n.18. Labor Petitioners present these arguments under the umbrella of their statutory argument, that Section 2605(b) prohibits the consideration of non-risk factors in a risk evaluation. But these are not arguments that EPA *cannot* consider personal protective equipment. These are arguments why EPA allegedly *should not* do so. And whether EPA should or should not consider personal protective equipment is unavoidably a fact- and context-specific inquiry. As such, Labor Petitioners' arguments are not facial but are as-applied challenges. *See, e.g., Ass'n of Private Sector Colls. and Univs. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012) (to prevail in a facial challenge to a regulation, petitioner must establish that no set of circumstances exists under which the regulation would be valid).

Labor Petitioners also argue that considering personal protective equipment in a risk evaluation is inconsistent with EPA's obligation to rely on the best available science and with OSHA's practice regarding personal protective equipment. Labor Br. at 25-28. Again, Labor Petitioners assert that these arguments are facial challenges, i.e., that the regulation is contrary to Section 2625(h)'s requirement that EPA base its decisions on the best available science. But Section 2625(h) says nothing about whether particular information about personal protective equipment or specific industry practices is, or is not, consistent with the best available science. That is quintessentially an as-applied challenge.

Industry and Intervenor Petitioners' as-applied challenges regarding personal protective equipment similarly are not ripe. Industry and Intervenor Petitioners argue that the 2024 Rule is unreasonable because it requires that EPA "refuse to account" for existing OSHA standards and personal protective equipment effectiveness and use. Intervenor Br. at 21; Industry Br. at 36. But the 2024 Rule on its face does not prohibit EPA from considering OSHA regulations or information on personal protective equipment use. To the contrary, the 2024 Rule requires EPA to consider all reasonably available information, and not *assume* personal protective equipment use when determining risk. *See* 40 C.F.R. § 702.39(f)(2). It is necessarily a case-by-case inquiry whether personal protective equipment, OSHA regulations, or other related information will be considered.

It is true that OSHA regulations are reasonably available information that EPA will consider in certain risk evaluations. But *what* regulations should be considered, whether they apply to all workers, whether they are sufficient to address the risk, and what weight they should be given in a particular risk evaluation are fact-specific inquiries. These are necessarily as-applied challenges that cannot be reviewed at this time. *See, e.g., Ass'n of Private Sector Colls.*, 681 F.3d at 442.

If EPA considers or fails to consider personal protective equipment in a particular risk determination in a manner that a petitioner believes is unlawful, then that party can challenge that specific determination. *See* 15 U.S.C. § 2618(a)(1)(A) (allowing petitions for review of a determination that a chemical substance does not present an unreasonable risk of injury to health or the environment, and of a risk management rule following a determination that a chemical substance does present an unreasonable risk). Such a challenge would be reviewed based on substantial evidence in the "rulemaking record taken as a whole" or the "record taken as a whole," depending on whether EPA's final action is a risk management rulemaking or a no unreasonable risk order. *See* 15 U.S.C. § 2618(c)(1)(B)(i)(I), (II). In either case, the reviewing court would have the benefit of a fully developed factual record. But when faced with "a challenge to the validity of the entire rule in all its applications," the fact that a petitioner "can

point to a hypothetical case in which the rule might lead to an arbitrary result" does not render the rule invalid. *Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 619 (1991) (rejecting facial challenge to agency rule despite possible arbitrary applications).

Petitioners' challenge to the reasonableness of the 2024 Rule is therefore not yet ripe. *Compare Safer Chemicals*, 943 F.3d at 413 (finding certain as-applied claims not ripe because it was not clear EPA would conduct its risk evaluations in manner petitioners feared).

IV. EPA must consider reasonably available information regarding workers' actual use of personal protective equipment, but EPA cannot rely on assumptions regarding such use.

When EPA evaluates risk, it must consider reasonably available information regarding human and environmental exposures arising from the chemical substance's conditions of use. Workers in occupational exposure scenarios may sometimes have reduced exposure to a chemical substance because they use personal protective equipment. But the availability, efficacy, and reliability of use of such equipment can vary widely. So, in the 2024 Rule, EPA stated that it would consider reasonably available information regarding personal protective equipment use and efficacy in assessing exposure but would not rely on assumptions of such use or efficacy when making a risk determination. 40 C.F.R. § 702.39(f)(2).

Sections 2605(b)(4)(F) and 2625(k) require EPA to consider the reasonably available information on hazards and exposures for a chemical substance's

conditions of use. In the context of occupational exposure assessments, the best reading of these sections is that reasonably available information includes information regarding personal protective equipment and other known exposure-reducing controls, existing regulatory requirements, as well as information that substantiates usage, fit, and effectiveness of personal protective equipment. Reasonably available information also includes information regarding the absence or ineffective use of personal protective equipment, or its failures to ensure that workers are adequately protected from exposure. But reliance on assumptions regarding personal protective equipment when determining risk is neither permitted by the statute, nor reasonable.

Labor and Industry Petitioners take opposite views of EPA's personal protective equipment regulation. Labor Petitioners argue that TSCA prohibits EPA from considering personal protective equipment as part of a risk evaluation, full stop. Conversely, Industry Petitioners argue that TSCA not only requires EPA to consider information regarding actual personal protective equipment usage, TSCA requires EPA to assume that such equipment is always used by all workers *and* is consistently effective in reducing or eliminating exposure. Neither extreme is supported by the statutory language.

Labor Petitioners and Industry Petitioners (joined by Intervenor Petitioner) also take opposite positions on the reasonableness of the 2024 Rule's framework

for considering reasonably available information about personal protective equipment. Both extremes again miss the mark. Contrary to Labor Petitioners' argument, EPA's approach does not underestimate workers' risk. Instead, EPA's consideration of reasonably available exposure-related information results in more accurate risk evaluations. And, contrary to Industry and Intervenor Petitioners' arguments, EPA's approach does not ignore information regarding the existence or applicability of OSHA regulations, industry compliance with those regulations, the variability of worker protection practices across facilities or sectors, or the effectiveness of personal protective equipment in protecting against exposures. Instead, the 2024 Rule clarifies that when making a risk determination, EPA will not assume workers' exposures are reduced due to such equipment. EPA's position is based on the best reading of the statute, and it is reasonable and well supported by the administrative record.

A. Even if Petitioners' as-applied challenges are ripe, their arguments do not succeed.

1. EPA's decision to consider information regarding personal protective equipment in a risk evaluation is reasonable.

Labor Petitioners argue that any consideration of personal protective equipment in the risk evaluation phase is necessarily arbitrary. Labor Petitioners present several of these arguments as interpretations of Section 2605(b)(4)(A)'s prohibition on considering nonrisk factors in a risk evaluation. Labor Br. at 21-25.

Other arguments are presented as interpretations of Section 2625(h)'s requirement that when EPA makes science-based decisions, EPA must use scientific information in a manner consistent with the best available science. *Id.* at 25-33. But each argument boils down to the same assertion, that practical considerations regarding personal protective equipment make the 2024 Rule unreasonable.

Labor Petitioners' arguments are not ripe. *See supra*, Argument III. If the Court nonetheless reaches the merits of this issue, Labor Petitioners' reasons why EPA should not consider personal protective equipment in the risk evaluation phase all suffer from the same basic flaw: it would be unreasonable, and in fact unlawful, for EPA to fail to consider reasonably available exposure information regarding the use and effectiveness of personal protective equipment in occupational settings.

Labor Petitioners argue that if EPA considers personal protective equipment, then EPA will invariably underestimate risk. Labor Br. at 20-21. But mere consideration of reasonably available information on personal protective equipment will not underestimate risks. Under the 2024 Rule, consideration of personal protective equipment will include all reasonably available information, including the very information that Labor Petitioners highlight about noncompliance, outdated standards, inapplicability to certain workers, and the ineffectiveness of personal protective equipment. Response to Comments at 34,

JAxxxx. Taking into consideration reasonably available information, whether it shows actual and effective use of personal protective equipment or not, results in more accurate exposure assessments and risk characterizations, and thus more accurate risk determinations.

Labor Petitioners next argue that the effectiveness of personal protective equipment depends on many variables. Labor Br. at 21-22. But variability is no reason to ignore reasonably available information on workers' exposures. Labor Petitioners also assert that considering personal protective equipment as part of the risk evaluation is inconsistent with the best available science. *Id.* at 25-28. This is not a basis for EPA to ignore information that demonstrates known or effective occupational exposure control practices in conducting an exposure assessment. While TSCA's science standards require EPA to weigh the scientific evidence under Section 2625(i), that does not negate EPA's obligation to consider reasonably available information on workers' exposures. 15 U.S.C. § 2625(i). If EPA has "information that demonstrates effective occupational exposure control practices," Response to Comments at 35, JAxxxx, EPA will consider that information as part of the risk evaluation, but when making a risk determination EPA will not assume those practices are always used. Thus, EPA cannot ignore available information showing personal protective equipment use and efficacy.

Labor Petitioners also argue there are "practical reasons" not to consider personal protective equipment during the risk evaluation. Labor Br. at 24. They cite two risk management rules where EPA stated that it cannot make assumptions about personal protective equipment. *See* proposed risk management rule for 1-Bromopropane (1-BP), 89 Fed. Reg. 65066 (Aug. 8, 2024) (EPA will not assume all facilities across all uses of the chemical will adopt personal protective equipment for "purposes of making the TSCA risk determination" so EPA instead uses industry practices that "are clearly articulated" as part of the risk management rule); proposed risk management rule for n-Methylpyrrolidone (NMP), 89 Fed. Reg. 51134 (June 14, 2024) (information regarding "different levels of mitigation" could be used during risk management because it is not reasonable to assume that all facilities would have adopted the same controls). But these statements are entirely consistent with the 2024 Rule, which prohibits EPA from basing a risk determination on assumptions regarding personal protective equipment use and effectiveness. *See* 89 Fed. Reg. at 37037/3 (encouraging companies to submit information on their occupational exposure control practices, including "the extent to which those practices may be standard for an industry"). In both of these risk management rules, consistent with the 2024 Rule, EPA considered the use of personal protective equipment as part of the exposure assessment, but EPA did not

assume across-the-board use and effectiveness of personal protective equipment when it made the risk determination.

Fourth, Labor Petitioners argue that personal protective equipment does not control the level of exposures in the workplace. Labor Br. at 25 n.18; *see also id.* at 26-27 (noting that OSHA has found respirators are "unreliable as protection against harmful chemicals"). EPA again agrees. Although proper use of personal protective equipment can, under the right circumstances, have the effect of reducing personal exposures to an individual worker, it does not prevent the chemical from continuing to be present in the workplace, and may or may not address the unreasonable risk identified by EPA in a risk evaluation. For example, workers might not be given the appropriate equipment, they might not wear the equipment for their entire shift, they might remove the equipment for specific tasks or for breaks, or they might otherwise be susceptible to continued exposure to the chemical in the workplace after the initial exposure event. The 2024 rule provides that EPA will consider reasonably available information regarding such circumstances as part of its evaluation.

Labor Petitioners also point to comments from OSHA, submitted to EPA in an individual risk evaluation, urging EPA to not consider personal protective equipment in that risk evaluation. Labor Br. at 8-10; *see also id.* at 27-28. OSHA's actual comment was that OSHA does not evaluate respirator impact in an

initial risk characterization because doing so would presume that all workers in an occupational group will be properly trained, fitted, and wear respirators, which is rarely the case. *See* EPA-HQ-OPPT-2023-0496-0215 at 6. This is entirely consistent with EPA's decision not to make assumptions regarding personal protective equipment for purposes of making a risk determination. Labor Petitioners also attached a comment from the National Institute for Occupational Safety and Health, again in the context of a specific risk evaluation for methylene chloride, not this rulemaking. That agency stated that EPA should calculate risks without regard for respiratory protection to encourage the use of the hierarchy of controls, which is a framework for risk management options that prefers engineering and work practice controls over respirators. *See* EPA-HQ-OPPT-2023-0496-0215 at 5. But TSCA requires EPA to assess chemical substances under the conditions of use, including the applicable exposures. EPA bases its evaluations and risk determinations on these statutory requirements.

2. EPA correctly understands employer obligations under the OSH Act.

Labor Petitioners' final reason why EPA acted arbitrarily is that, according to Labor Petitioners, EPA understood "OSHA regulations to impose some universal duty to provide" personal protective equipment. Labor Br. at 28; *see also id.* at 31 (referring to "EPA's apparent assumption that the respirator standard requires employers to provide effective protection"); *id.* at 33 (arguing that EPA

erred "to the extent EPA is proceeding from an assumption that OSHA standards impose an obligation on employers to provide respirators to protect their employees from all levels of exposure"). That is inaccurate. Again, the 2024 Rule merely provides that EPA will consider reasonably available information about personal protective equipment when conducting risk evaluations, and prohibits EPA, when determining risk, from *assuming* that workers always and effectively use personal protective equipment.

Labor Petitioners' litany of reasons why OSHA standards may not be fully protective, Labor Br. at 29-32, does not mean that the 2024 Rule is arbitrary. To the contrary, Labor Petitioners' arguments support EPA's decision not to make assumptions regarding exposure reductions when making a risk determination, even if there are OSHA regulations applicable to the chemical undergoing risk evaluation.

In sum, Labor Petitioners' arguments regarding the ineffectiveness of personal protective equipment do not override TSCA's requirement that EPA consider exposure information as part of the risk evaluation process. Information regarding personal protective equipment is relevant "information on hazards and exposures" under Section 2605(b)(4)(F)(i), relevant information on "the likely duration, intensity, frequency, and number of exposures" under Section 2605(b)(4)(F)(iv), and relevant "hazard and exposure information" under Section

2625(k). EPA's interpretation that TSCA requires EPA to consider such information in a risk evaluation is therefore the best reading of the statute and a reasonable approach.

3. EPA reasonably considers information regarding actual personal protective equipment usage, rather than assuming such usage when making risk determinations.

Industry and Intervenor Petitioners also argue that EPA *must* make assumptions about personal protective equipment, and that the 2024 Rule is arbitrary because it states that EPA will not assume that personal protective equipment is always used, or that it is always effective in reducing workers' exposure.

First, Industry and Intervenor Petitioners argue that it is irrational for EPA to assume noncompliance with OSHA requirements and consider that some employees are outside OSHA's regulations. Industry Br. at 36; Intervenor Br. at 20. But again, EPA is not assuming anything. Rather, the 2024 Rule requires EPA to look at the reasonably available information on personal protective equipment use. And the administrative record is clear that noncompliance does occur. *See* Response to Comments at 31, JAxxxx. Moreover, even with compliance, some OSHA standards are outdated (with most chemical-specific standards dating from the 1970s), do not cover all workers involved in the conditions of use assessed in a risk evaluation, or require an insufficient level of protection to address the

unreasonable risk identified by EPA under TSCA. *Id.* at 32, JAxxxx; *see also* 89 Fed. Reg. at 37037/2. OSHA itself acknowledges the limits of its authority to regulate exposures to hazardous chemicals, because OSHA lacks direct jurisdiction over certain workers. *See, e.g.*, *Standard Interpretation, Application of OSHA requirements to self-employed construction workers*, Occupational Safety and Health Administration, https://www.osha.gov/laws-regs/standardinterpretations/2001-05-23-3.

Finally, Intervenor Petitioner argues that EPA's "no-[personal protective equipment] assumption" arbitrarily overestimates risk. Again, this mischaracterizes the requirement in the 2024 Rule, which prohibits consideration of worker exposure reduction as part of the risk determination, based on assumed use of personal protective equipment. It does not instruct EPA to make a "*no PPE assumption*." 89 Fed. Reg. at 37037. Rather, EPA will consider the available information repeatedly discussed about personal protective equipment use and efficacy.

B. EPA is required to consider reasonably available information on use and effectiveness of personal protective equipment in a risk evaluation.

When EPA conducts a risk evaluation, Section 2605(b)(4)(F)(i) requires EPA to "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance," including information on

potentially exposed or susceptible subpopulations that EPA identifies. 15 U.S.C. § 2605(b)(4)(F)(i).

Similarly, Section 2605(b)(4)(F)(iv) requires EPA to "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F)(iv). And Section 2625(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(k).

As a factual matter, the availability, use, and efficacy of personal protective equipment is relevant to chemical exposure. Thus, if a risk evaluation were to ignore reasonably available information regarding personal protective equipment usage, then EPA would fail to "integrate and assess," "take into account," and "take into consideration" information regarding exposures.

So, to clarify that information regarding usage of personal protective equipment is reasonably available exposure information, the 2024 Rule states that when EPA considers occupational exposure scenarios in making a risk determination, EPA will "take into account … known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment." 40 C.F.R. § 702.39(f)(2).

This regulatory text implements the plain meaning of Section 2605(b)(4)(F) and Section 2625(k), directing EPA to "integrate and assess," "take into account," and "take into consideration" exposure information. And with that obligation, EPA cannot ignore reasonably available exposure information. Effective use of personal protective equipment is one way that some employers address and reduce some workers' exposure to chemical substances in the workplace. *See* 88 Fed. Reg. 74292, 74304. Thus, information regarding workers' use of personal protective equipment as well as information that substantiates the use, fit, and effectiveness of such equipment must be considered. *See* 89 Fed. Reg. at 37037/3 (information about "occupational exposure control practices" such as personal protective equipment usage is relevant to a risk evaluation's exposure assessment).

Labor Petitioners disagree. They argue that Section 2605(b)(4)(A) completely precludes EPA from considering personal protective equipment in a risk evaluation. Labor Br. at 18. Specifically, they contend that considering personal protective equipment amounts to considering "non-risk factors," which Section 2605(b)(4)(A) prohibits. Labor Br. at 18-19 (citing 15 U.S.C. § 2605(b)(4)(A)); *see also id.* at 20-21 (arguing that empirical data on personal protective equipment usage is a non-risk factor and thus irrelevant in a risk evaluation). To be sure, personal protective equipment is, as Labor Petitioners argue (*see* Labor Br. at 30), also a potential control measure—that is, a way to

manage unreasonable risk under Section 2605(a). *See* Response to Comments at 31, JAxxxx; 88 Fed. Reg. at 74305/1; 89 Fed. Reg. at 37037/3 (information from the risk evaluation's exposure assessment is also considered in the risk management phase). But personal protective equipment is a risk factor because it is information regarding worker exposure. Put differently, using personal protective equipment can reduce exposure and thus reduce risk, and so, in appropriate circumstances, should be considered when evaluating risk.

EPA is not conflating a risk evaluation with risk management, as Labor Petitioners assert. Labor Br. at 20. Incorporating reasonably available information regarding personal protective equipment into the exposure assessments and risk characterizations results in more accurate assessments and thus more accurate risk determinations. Reasonably available information about the use of personal protective equipment and its potential to reduce exposure to workers is information about exposure and thus a risk factor that EPA must consider as part of the risk evaluation. For example, EPA stated that, in circumstances where the reasonably available information demonstrates that performance of a condition of use is impossible without the effective use of personal protective equipment, the use and effectiveness of such equipment will be considered throughout the risk evaluation, including in the risk determination. 88 Fed. Reg. at 74305.

Labor Petitioners also argue that EPA itself has recognized personal protective equipment is a non-risk factor. Labor Br. at 23. In fact, EPA considers personal protective equipment both as a potential exposure control for risk management, and as information relevant to exposures in the risk evaluation. Labor Petitioners cite a passage in the preamble to the 2024 Rule where EPA states that it "does not take into account any existing occupational exposure controls" in deriving its "risk-based occupational exposure value[s]," but that EPA will consider "existing occupational exposure control approaches" during the risk management phase. *Id.* at 23-24, quoting 89 Fed. Reg. at 37040/3. This passage addresses the occupational exposure value[1], which is based on the "most sensitive hazard endpoint." EPA calculates this value without considering personal protective equipment, so as to capture the most sensitive workers, i.e., ones not using the personal protective equipment. EPA's statement that the occupational exposure value "does not take into account any existing occupational exposure controls" refers to the risk management phase, where EPA has already determined that a given condition of use significantly contributes to the unreasonable risk finding. Thus, EPA starts from a baseline in which no exposure control is used.

[1] EPA calculates an occupational exposure value in the risk evaluation primarily to support future risk management efforts, if necessary. The value represents an exposure value without any existing occupational exposure controls. The occupational exposure value is not a number that influences EPA's risk determination.

But, as EPA states in the next paragraph in the preamble, EPA will give "additional consideration of exposures and non-risk factors consistent with" risk management rules promulgated pursuant to Section 2605(c). *See* 89 Fed. Reg. at 37040/3. In other words, EPA considers exposure controls such as personal protective equipment in the risk evaluation, and then gives such controls "additional consideration" during the risk management phase.

Labor Petitioners point out that OSHA—an agency that also quantifies risk—considers personal protective equipment only as a work practice that manages risk, not as a means of measuring risk. Labor Br. at 21; *see also id.* at 26 (noting that OSHA defines risk without regard to personal protective equipment). But risk evaluations under TSCA are subject to different requirements, that uniquely require EPA to consider information related to the intensity, frequency, and duration of exposure. The manner in which OSHA addresses risk under the OSH Act cannot override TSCA's requirements, including the requirement that EPA assess exposure information.

Labor Petitioners likewise point to two court decisions that evaluated personal protective equipment usage as part of an analysis of technological feasibility—a non-risk factor—instead of as a factor relevant to estimating risk. Labor Br. at 23. But each case addressed personal protective equipment as it related to risk management and did not address whether personal protective

equipment can be considered in a risk evaluation. *See United Steelworkers of Am., v. Marshall*, 647 F.2d 1189, 1269 (D.C. Cir. 1980) (noting that the hierarchy of controls, a framework for risk management options, prefers engineering and work practice controls over respirators); *Am. Iron & Steel Inst. v. OSHA*, 182 F.3d 1261, 1267–68 (11th Cir. 1999) (same). As noted above, personal protective equipment and its potential to reduce exposure to workers is information about exposure and thus a risk factor that EPA must consider as part of a risk evaluation.

C. EPA cannot rely on assumptions regarding personal protective equipment.

At the other end of the spectrum, Industry and Intervenor Petitioners argue that EPA *must* assume that all workers have and use personal protective equipment correctly and effectively. This opposite approach is just another way to force EPA to bury its head in the sand, this time by ignoring available information that shows that workers do not always have—or that they do not always properly use—personal protective equipment, as well as information that such equipment is often ineffective. EPA's approach is the best application of the statute and the most responsive to facts.

Just as the statute does not allow EPA to ignore information about personal protective equipment, the statute does not permit a blanket assumption that all workers always and effectively use appropriate personal protective equipment, or that such equipment necessarily reduces their exposure, in making a risk

determination. Section 2605(b) requires EPA to evaluate the chemical substance under the intended, known, or reasonably foreseen circumstances. 88 Fed. Reg. at 74304/2. A blanket assumption about personal protective equipment, without supporting reasonably available information, does not "reflect the known or reasonably foreseen chemical exposures that impact workers." *Id.* Thus, the final sentence in the regulatory text added by the 2024 Rule states: EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination. 40 C.F.R. § 702.39(f)(2).

Industry Petitioners argue that workers' usage of personal protective equipment is "clearly relevant to the analysis of exposure and its contribution to workplace risk." Industry Br. at 37. EPA agrees, and as explained above, cannot ignore such information. *See supra*, Argument IV.A.1. But a requirement to consider information that shows such equipment is always and effectively used does not equate to a requirement to assume such use and effectiveness in making a risk determination. That is especially true because TSCA requires EPA to base risk determinations on potentially exposed or susceptible subpopulations, which expressly includes workers. And the administrative record shows that not all workers have and use effective personal protective equipment.

Put another way, EPA can consider information about the exposure reducing benefits of personal protective equipment in the exposure assessment, but when

EPA makes a risk determination EPA cannot assume, without supporting information, that every worker in an occupational exposure scenario is always provided with and appropriately wears such personal protective equipment. Instead, EPA must weigh all the reasonably available information, including information regarding inconsistent practices across employers and facilities, the effectiveness of the equipment, inapplicability of and/or noncompliance with applicable regulatory standards, and so on.

Industry Petitioners next argue that EPA is imposing a "requirement to ignore the use of required" personal protective equipment and thus is not considering reasonably available information. Industry Br. at 37. Far from turning a "blind eye," *id*., the 2024 Rule provides that if EPA has information regarding personal protective equipment, EPA will consider that information in its exposure assessment. 40 C.F.R. § 702.39(f)(2). And, as described below, the administrative record shows that not every employer must comply with OSHA regulations (e.g., when working with independent contractors, *Standard Interpretation, Application of OSHA requirements to self-employed construction workers*, Occupational Safety and Health Administration, https://www.osha.gov/laws-regs/standardinterpretations/2001-05-23-3) and that even then, workers do not always use appropriate personal protective equipment. *See also supra*, Argument IV.A. Furthermore, risk evaluations under TSCA are subject to multiple statutory

science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk facts when determining whether a chemical presents unreasonable risk that warrants regulatory actions. 89 Fed. Reg. 37037/2. None of these requirements apply to the development of OSHA regulations.

Industry Petitioners also claim that considering actual information regarding personal protective equipment, but not assuming its use, ignores the definition of conditions of use. According to Industry Petitioners, speculative misuse or non-use of personal protective equipment in every case is "illogical." Industry Br. at 38. That might be true if the 2024 Rule assumed non-use of personal protective equipment. But the 2024 Rule neither assumes use nor assumes non-use of personal protective equipment. And, as discussed below, the administrative record demonstrates that EPA is not speculating: many OSHA regulations are decades out of date, and not all employers or workers are covered under the OSH Act. Response to Comments at 32, JAxxxx (where there is a failure of an employer to provide its workers personal protective equipment at all, or the appropriate type of equipment for the particular task, or properly fitting equipment for the particular worker, or where there is a functional failure of the equipment, none of these circumstances can reasonably be characterized as intentional misuse).

Industry Petitioners argue that EPA can reasonably obtain OSHA regulations that address personal protective equipment requirements. Industry Br. at 38. That misses the point. EPA agrees that OSHA regulations are reasonably available information regarding workers' potential exposure and as such, are considered in a risk evaluation where appropriate. But for the reasons explained above, those regulations by themselves are not probative of workers' exposure.

Industry Petitioners also argue that if EPA "ignores" personal protective equipment, the resulting risk evaluations will not follow the best available science and will overestimate risk by overestimating exposure, leading to bad risk management decisions that are not based on science. *Id*. at 38. Similarly, Industry Petitioners argue that the consequence is unreasonable risk determinations for every chemical EPA evaluates, which Industry Petitioners assert is contrary to TSCA and to congressional intent. *Id*. at 39-41. But again, EPA is not ignoring reasonably available information regarding personal protective equipment in its risk evaluations.

Instead, the 2024 Rule firmly commits EPA to consider reasonably available information, and, as Sections 2625(h) and (i) require, to base its decisions on the weight of the scientific evidence consistent with the best available science. *See* 15 U.S.C. § 2625(h), (i) (scientific information must be "employed in a manner consistent with the best available science" and EPA must make decisions based on

the weight of the scientific evidence). Therefore, the claim by Industry Petitioners that the 2024 Rule will lead to unreasonable risk determinations "for every chemical EPA evaluates" is both speculative and unfounded. Further, while Industry Petitioners' speculation on hypothetical risk management approaches are not relevant to the 2024 Rule, the 2024 Rule nevertheless establishes a framework for EPA to complete risk evaluations that are supported by the reasonably available information, based on the weight of the scientific evidence, and therefore establish sound scientific bases for risk management rules.

Industry Petitioners next accuse EPA of ignoring Section 9(d)'s requirement to consult and coordinate with OSHA. Industry Br. at 38, citing 15 U.S.C. § 2608(d) (EPA shall consult in order to achieve "maximum enforcement of this chapter while imposing the least burdens of duplicative requirements"). But not assuming use of personal protective equipment does not equate to a failure to consult. In fact, the 2024 Rule expressly provides for and promotes interagency collaboration. *See* 40 C.F.R. § 702.47 ("During the risk evaluation process, not to preclude any additional, prior, or subsequent collaboration, EPA will consult with other relevant Federal agencies"); 88 Fed. Reg. at 74304-05 ("EPA will proactively communicate with Federal agencies [to meet TSCA requirements], while also leveraging ongoing interagency dialogue and striving to avoid potential impacts to mission and infrastructure critical uses"). Thus, OSHA, and other federal agencies,

will have the opportunity to provide information demonstrating that personal protective equipment is effectively and reliably used.

Industry Petitioners also assert that EPA should "defer to OSHA's primary authority" instead of "overreach into an area that Congress delegated to OSHA for regulation." Industry Br. at 39. Contrary to Industry Petitioners' assertions, Congress expressly included "workers" as an example of a potentially exposed or susceptible subpopulation. *See* 15 U.S.C. § 2602(12). Congress's inclusion of workers in the definition of "potentially exposed or susceptible subpopulation," and explicit instruction to "determine whether a chemical substance presents an unreasonable risk … including an unreasonable risk to a potentially exposed or susceptible subpopulation" is indicative of its intent that EPA evaluate risks to workers. *See id.* §§ 2602(12), 2605(b)(4)(A).

Industry Petitioners further appear to point to discretion conferred by Section 2608(a) that permits EPA to refer an unreasonable risk to another agency for risk management. But that discretionary authority is only available after EPA conducted the risk evaluation and makes the underlying unreasonable risk determination. It is not authority to refer the actual risk evaluation to another agency. 15 U.S.C. § 2608(a)(1). Furthermore, any such referral is contingent on a determination, that by statute is expressly "in the Administrator's discretion,"

whether "action taken under a Federal law not administered by" EPA may prevent or reduce the risk "to a sufficient extent." *Id.*

Finally, Intervenor Petitioner cites *Maine Lobstermen's Association v. National Marine Fisheries Service*, 70 F.4th 582, 598-99 (D.C. Cir. 2023), for the proposition that a policy-based presumption is impermissible. Intervenor Br. at 21. In *Maine Lobstermen's*, the Fish and Wildlife Service utilized modeling focused on the worst-case scenario when faced with data uncertainties. *Me. Lobstermen's Ass'n*, 70 F.4th at 590. This Court found that approach unreasonable and contrary to law where the regulations required the Service to determine "effects … reasonably certain to occur … based on clear and substantial information." *Id.* at 598 (quoting 50 C.F.R. §§ 402.02, 402.17(b)). The 2024 Rule does not require EPA to consider the "worst case scenario," like the regulation at issue in *Maine Lobstermen's*. Rather, the 2024 Rule embodies exactly what this Court found in *Maine Lobstermen's*. When a statute directs an agency to use the best available scientific data, the agency should not presume the lack of data weighs one way or another. *Id.* at 599. The 2024 Rule instructs EPA to presume nothing and consider the actual information reasonably available. The information available to EPA, as described, is clear that personal protective equipment is not perfectly or universally used in all scenarios. Thus, considering *actual* usage instead of assuming *perfect*

and universal usage is a reasonable way to take personal protective equipment into account.

V. Intervenor Petitioner's argument about EPA's inclusion of overburdened communities is not ripe, and is wrong on the merits.

As with petitioners' arguments regarding the reasonableness of EPA's framework for considering information about personal protective equipment, Intervenor Petitioner's argument about the inclusion of overburdened communities is not ripe.

Section 2602(12) provides EPA with the express charge to identify potentially exposed or susceptible subpopulations. 15 U.S.C. § 2602(12) ("a group of individuals within the general population *identified by the Administrator* … such as infants, children, pregnant women, workers, or the elderly") (emphasis added). Thus, EPA has the discretion to interpret those terms on a case-by-case, chemical specific basis, and identify any subpopulation based on these statutory criteria, irrespective of the examples provided in the statute and regulations. *See* 88 Fed. Reg. at 74306. This is a discretionary authority that EPA has often practiced in past risk evaluations. *See, e.g.*, Risk Evaluation for n-Methylpyrrolidone, at 215 (identifying men and women of reproductive age as a potentially exposed or susceptible subpopulation), JAxxxx.

The inclusion of "overburdened communities" is not a determination that all communities disproportionately exposed or impacted by environmental harms will

be considered a potentially exposed or susceptible subpopulation. Rather, it is provided as an example of a potentially exposed or susceptible subpopulation that EPA *may* choose to consider in future risk evaluations where appropriate. EPA included this example to reflect its "understanding and acknowledgement that exposure to a chemical substance may disproportionately impact communities already experiencing disproportionate and adverse human health or environmental burdens." 88 Fed. Reg. at 74306. Thus, identification of overburdened communities as a potentially exposed or susceptible subpopulation in a chemical's risk evaluation is necessarily an as-applied challenge and is not ripe for review without consideration of specific factual circumstances not yet available for review.

Even if Intervenor Petitioner's argument is ripe, it fails on the merits. Intervenor Petitioner argues that EPA's inclusion of "overburdened communities" as an example of potentially exposed or susceptible subpopulations results in EPA improperly authorizing itself to consider population-specific risks not based on exposure or susceptibility. This is incorrect. The regulatory text explicitly provides overburdened communities as one example among several others, after reciting the statutory criteria for potentially exposed or susceptible subpopulations. 40 C.F.R. § 702.33; 15 U.S.C. § 2605(b)(4)(A). Section 2602's definition of potentially exposed or susceptible subpopulation does not define the terms "greater

susceptibility" or "greater exposure." *See* 15 U.S.C. § 2602(12). Additionally, as explained above, overburdened communities was simply provided as an example, and the determination whether to consider overburdened communities as a potentially exposed or susceptible subpopulation will be made case-by-case in each risk evaluation.

EPA's inclusion of overburdened communities as an example of a potentially exposed or susceptible subpopulation does not provide EPA with more authority than that granted by Congress. Rather, it provides transparency and clarity on EPA's potential future decision making.

CONCLUSION

The Court should dismiss in part and deny in part the petitions for review.

Respectfully submitted on December 20, 2024.

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CERTIFICATES OF COMPLIANCE AND SERVICE

I certify that this brief complies with Fed. R. App. P. 32(a)(5) and (6) because it uses 14-point Times New Roman, a proportionally spaced font.

I also certify that this brief complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B) because by Microsoft Word's count, it has 19,407 words, excluding the parts of the brief exempted under Rule 32(f).

Finally, I certify that on December 20, 2024, I electronically filed this brief with the Court's CM/ECF system, which will serve each party.

/s/ Daniel R. Dertke
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STATUTORY AND REGULATORY ADDENDUM

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15 U.S.C.A. § 2601

§ 2601. Findings, policy, and intent

Effective: June 22, 2016
Currentness

(a) Findings

The Congress finds that--

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) Policy

It is the policy of the United States that--

(1) adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that

such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

(c) Intent of Congress

It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter.

CREDIT(S)

(Pub.L. 94-469, Title I, § 2, Oct. 11, 1976, 90 Stat. 2003; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, §§ 2, 19(b), June 22, 2016, 130 Stat. 448, 505.)

Notes of Decisions (5)

15 U.S.C.A. § 2601, 15 USCA § 2601
Current through P.L. 118-137. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2604

§ 2604. Manufacturing and processing notices

Effective: June 22, 2016
Currentness

(a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may--

(i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if--

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator--

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including--

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Review and determination

Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine--

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the

submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) Failure to render determination

(A) Failure to render determination

If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) Limitations

(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) Article consideration

The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) Submission of information

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit information for such substance pursuant to a rule, order, or consent agreement under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If--

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule or order under section 2603 of this title before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(2)(A) If a person--

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule, order, or consent agreement under section 2603 of this title before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that--

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(A)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including--

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of Title 5.

(c) Extension of review period

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b). Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of notice; publications in the Federal Register

(1) The notice required by subsection (a) shall include--

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information under subsection (b), the Administrator shall publish in the Federal Register a notice which--

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)(A) If the Administrator determines that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

(B) An order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the applicable review period, and (ii) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(2) Repealed. Pub.L. 114-182, Title I, § 5(5)(D), June 22, 2016, 130 Stat. 458

(f) Protection against unreasonable risks

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)--

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) Treatment of nonconforming uses

Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) Workplace exposures

To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) Statement on Administrator finding

If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes--

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that--

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, then (unless such person and the persons referred to in clauses (i) and (ii)

agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)--

(i) to the person who previously submitted the information on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information for a chemical substance is a period--

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such information to the Administrator, and

(ii) ending--

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such information,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of--

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definitions

(1) For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(2) For purposes of this chapter, the term "requirement" as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term "applicable review period" means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

CREDIT(S)

(Pub.L. 94-469, Title I, § 5, Oct. 11, 1976, 90 Stat. 2012; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, §§ 5, 19(e), June 22, 2016, 130 Stat. 454, 506.)

Notes of Decisions (1)

15 U.S.C.A. § 2604, 15 USCA § 2604
Current through P.L. 118-137. Some statute sections may be more current, see credits for details.

End of Document

the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) of this section to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a) and (b) of this section do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 2605(c) of this title.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) of this section inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definitions

For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(Pub. L. 94-469, § 5, Oct. 11, 1976, 90 Stat. 2012.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2603, 2606, 2607, 2611 to 2613, 2614, 2616 to 2620, 2623, 2625, 2630 of this title.

§ 2605. Regulation of hazardous chemical substances and mixtures

(a) Scope of regulation

If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use

or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) Quality control

If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

(2) if the Administrator determines—

(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or

(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

(c) Promulgation of subsection (a) rules

(1) In promulgating any rule under subsection (a) of this section with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not pro-

mulgate a rule under subsection (a) of this section to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this chapter. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this chapter and under such law (or laws), and (iii) the relative efficiency of actions under this chapter and under such law (or laws) to protect against such risk of injury.

(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3); (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in section 2618(a) of this title), and (E) make and publish with the rule the finding described in subsection (a) of this section.

(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:

(A) Subject to subparagraph (B), an interested person is entitled—

(i) to present such person's position orally or by documentary submissions (or both), and

(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal hearing under this subsection. Such transcript shall be available to the public.

(4)(A) The Administrator may, pursuant to rules prescribed by the Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) of this section to any person—

(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

(ii) if—

(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—

(i) would be regulated by the proposed rule, or

(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

(5) Paragraph (1), (2), (3), and (4) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a) of this section.

(d) Effective date

(1) The Administrator shall specify in any rule under subsection (a) of this section the date on which it shall take effect, which date shall be as soon as feasible.

(2)(A) The Administrator may declare a proposed rule under subsection (a) of this section to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

(i) the Administrator determines that—

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c) of this section, for a hearing on such rule, and either promulgate such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.

(e) Polychlorinated biphenyls

(1) Within six months after January 1, 1977, the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)—

(i) no person may manufacture any polychlorinated biphenyl after two years after January 1, 1977, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after October 11, 1976.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c) of this section.

(5) This subsection does not limit the authority of the Administrator, under any other provision of this chapter or any other Federal law,

to take action respecting any polychlorinated biphenyl.

(Pub. L. 94-469, § 6, Oct. 11, 1976, 90 Stat. 2020.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2603, 2604, 2606 to 2608, 2611, 2612, 2614, 2616 to 2620, 2623, 2630 of this title.

§ 2606. Imminent hazards

(a) Actions authorized and required

(1) The Administrator may commence a civil action in an appropriate district court of the United States—

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b) of this section) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a rule under section 2603, 2604, or 2605 of this title or an order under section 2604 of this title, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this chapter.

(2) If the Administrator has not made a rule under section 2605(a) of this title immediately effective (as authorized by section 2605(d)(2)(A)(i) of this title) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) Relief authorized

(1) The district court of the United States in which an action under subsection (a) of this section is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) of this section brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) of this section against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and consolidation

(1)(A) An action under subsection (a) of this section against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia, or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) of this section against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) of this section in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpeonas requiring attendance of witnesses in an action brought under subsection (a) of this section may be served in any judicial district.

(2) Whenever proceedings under subsection (a) of this section involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) Action under section 2605

Where appropriate, concurrently with the filing of an action under subsection (a) of this section or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 2605(a) of this title.

(e) Representation

Notwithstanding any other provision of law, in any action under subsection (a) of this section, the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) Definition

For the purposes of subsection (a) of this section, the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk.

(Pub. L. 94-469, § 7, Oct. 11, 1976, 90 Stat. 2026.)

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Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 702. General Practices and Procedures (Refs & Annos)
Subpart A. Procedures for Prioritization of Chemical Substances for Risk Evaluation (Refs & Annos)

40 C.F.R. § 702.5

§ 702.5 Candidate selection.

Effective: September 18, 2017
Currentness

(a) General objective. In selecting candidates for a High–Priority Substance designation, it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first, considering reasonably available information on the relative hazard and exposure of potential candidates. In selecting candidates for Low–Priority Substance designation, it is EPA's general objective to select those chemical substances with hazard and/or exposure characteristics under the conditions of use such that a risk evaluation is not warranted at the time to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

(b) Available information. EPA expects to ensure that there is reasonably available information to meet the deadlines for prioritization under the Act.

(c) Preferences and TSCA work plan. In selecting a candidate for prioritization as a High–Priority Substance, EPA will:

(1) Give preference to:

(i) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a persistence and bioaccumulation score of 3; and

(ii) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity; and

(2) Identify a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as either a High–Priority Substance or Low–Priority Substance pursuant to § 702.11.

(d) Purpose. The purpose of the preferences and criteria in paragraphs (a) through (c) of this section is to inform EPA's decision whether or not to initiate the prioritization process pursuant to § 702.7, and the proposed designation of the chemical substance as either a High–Priority Substance or a Low–Priority Substance pursuant to § 702.9.

(e) Insufficient information. If EPA believes it would not have sufficient information for purposes of prioritization, EPA generally expects to obtain the information necessary to inform prioritization prior to initiating the process pursuant to § 702.9, using voluntary means of information gathering and, as necessary, exercising its authorities under the Act in accordance with the requirements of 15 U.S.C. 2603, 15 U.S.C. 2607, and 15 U.S.C. 2610. In exercising its authority under 15 U.S.C. 2603(a)(2), EPA will identify the need for the information in accordance with 15 U.S.C. 2603(a)(3).

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Current through December 12, 2024, 89 FR 100660. Some sections may be more current. See credits for details.

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Subchapter R. Toxic Substances Control Act
Part 702. General Practices and Procedures (Refs & Annos)
Subpart A. Procedures for Prioritization of Chemical Substances for Risk Evaluation (Refs & Annos)

40 C.F.R. § 702.7

§ 702.7 Initiation of prioritization process.

Effective: September 18, 2017
Currentness

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that the information necessary to prioritize the substance is reasonably available.

(b) EPA will initiate prioritization by publishing a notice in the Federal Register identifying a chemical substance for prioritization. EPA will include a general explanation in this notice for why it chose to initiate the process on the chemical substance.

(c) The prioritization timeframe in § 702.1(d) begins upon EPA's publication of the notice described in paragraph (b) of this section.

(d) Publication of the notice in the Federal Register pursuant to paragraph (b) of this section will initiate a period of 90 days during which interested persons may submit relevant information on that chemical substance. Relevant information might include, but is not limited to, any information that may inform the screening review conducted pursuant to § 702.9(a). EPA will open a separate docket for each chemical substance to facilitate receipt of information.

(e) EPA may, in its discretion, extend the public comment period in paragraph (d) of this section for up to three months in order to receive or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B). The length of the extension will be based upon EPA's assessment of the time necessary for EPA to receive and/or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B).

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

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Subpart B. Procedures for Chemical Substance Risk Evaluations (Refs & Annos)

40 C.F.R. § 702.43

§ 702.43 Risk evaluation actions and timeframes.

Effective: July 2, 2024
Currentness

(a) Draft scope.

(1) For each risk evaluation to be conducted, EPA will publish a document that specifies the draft scope of the risk evaluation EPA plans to conduct and publish a notice of availability in the Federal Register. The document will address the elements in § 702.39(b).

(2) EPA generally expects to publish the draft scope during the prioritization process concurrent with publication of a proposed designation as a High–Priority Substance pursuant to § 702.9(g), but no later than 3 months after the initiation of the risk evaluation process for the chemical substance.

(3) EPA will allow a public comment period of no less than 45 calendar days during which interested persons may submit comment on EPA's draft scope. EPA will open a docket to facilitate receipt of public comments.

(b) Final scope.

(1) EPA will, no later than 6 months after the initiation of a risk evaluation, publish a document that specifies the final scope of the risk evaluation EPA plans to conduct, and publish a notice of availability in the Federal Register. The document shall address the elements in § 702.39(b).

(2) For a chemical substance designated as a High–Priority Substance under subpart A of this part, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(c) Draft risk evaluation. EPA will publish a draft risk evaluation, publish a notice of availability in the Federal Register, open a docket to facilitate receipt of public comment, and provide no less than a 60–day comment period, during which time the public may submit comment on EPA's draft risk evaluation. The document shall include the elements in § 702.39(c) through (f).

(d) Final risk evaluation.

(1) EPA will complete and publish a final risk evaluation for the chemical substance under the conditions of use as soon as practicable, but not later than 3 years after the date on which EPA initiates the risk evaluation. The document shall include the elements in § 702.39(c) through (f) and EPA will publish a notice of availability in the Federal Register.

(2) EPA may extend the deadline for a risk evaluation for not more than 6 months. The total time elapsed between initiation of the risk evaluation and completion of the risk evaluation may not exceed 3- and one-half years.

(e) Final determination of unreasonable risk. Upon determination by the EPA pursuant to § 702.39(f) that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA will initiate action as required pursuant to 15 U.S.C. 2605(a).

(f) Final determination of no unreasonable risk. A determination by the EPA pursuant to § 702.39(f) that the chemical substance does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.

(g) Substantive revisions to scope documents and risk evaluations. The circumstances under which EPA will undertake substantive revisions to scope and risk evaluation documents are as follows:

(1) Draft documents. To the extent there are changes to a draft scope or draft risk evaluation, EPA will describe such changes in the final document.

(2) Final scope. To the extent there are changes to the scope of the risk evaluation after publication of the final scope document, EPA will describe such changes in the draft risk evaluation, or, where appropriate and prior to the issuance of a draft risk evaluation, may make relevant information publicly available in the docket and publish a notice of availability of that information in the Federal Register.

(3) Final risk evaluation. For any chemical substance for which EPA has already finalized a risk evaluation, EPA will generally not revise, supplement, or reissue a final risk evaluation without first undergoing the procedures at § 702.7 to re-initiate the prioritization process for that chemical substance, except where EPA has determined it to be in the interest of protecting human health or the environment to do so, considering the statutory responsibilities and deadlines under 15 U.S.C. 2605.

(4) Process for revisions to final risk evaluations. Where EPA determines to revise or supplement a final risk evaluation pursuant to paragraph (g)(3) of this section, EPA will follow the same procedures in this section including publication of a new draft and final risk evaluation and solicitation of public comment in accordance with §§ 702.43(c) and (d), and peer review, as appropriate, in accordance with § 702.41.

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Notes of Decisions (1)

Current through December 12, 2024, 89 FR 100660. Some sections may be more current. See credits for details.

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40 C.F.R. § 702.47

§ 702.47 Interagency collaboration.

Effective: July 2, 2024
Currentness

During the risk evaluation process, not to preclude any additional, prior, or subsequent collaboration, EPA will consult with other relevant Federal agencies.

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Current through December 12, 2024, 89 FR 100660. Some sections may be more current. See credits for details.

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